U.S. DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI as parent-guardians and next friend to their minor children, D.W.L., R.F.K., and C.K.K.; SHANNON LAPORTE, as parent-guardian and next friend to her minor children, M.T.L. and E.M.O.; and LYNNETTE WIEGAND, as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W., and M.L.W.,

Plaintiffs,

v

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES;ELIZABETH HERTEL, sued in her official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

Defendants.

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T. MORRIS

**STATE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Respectfully submitted,

DANA NESSEL
Attorney General

*/s/Aaron W. Levin*
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P.O. Box 30736
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(517) 335-7632

Dated: April 5, 2021

**STATE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Pursuant to Fed. R. Civ. P. 56, Defendants Director Elizabeth Hertel, Dr. Sandip Shah, Dr. Sarah Lyon-Callo, and Mary Kleyn, in their official capacities (collectively, the "State Defendants"), move that this Court grant summary judgment in favor of Defendants. The State Defendants say in support:

1. Plaintiffs have either affirmatively consented to the Michigan Department of Health and Human Services' program that makes retained residual dried blood spots available for research purposes, or failed to request that the retained dried blood spots be destroyed. In either case, the retained dried blood spots have not been used contrary to Plaintiffs' expressed directives.
2. The retention of residual dried blood spots has not interfered with any Plaintiff's ability to direct his or her family's medical care under the Fourteenth Amendment. To the extent it might have interfered with that ability, the program is narrowly tailored to further a compelling government interest.

3. The retention of residual dried blood spots is not a search or seizure under the Fourth Amendment. To the extent retention does constitute a search or seizure, it is reasonable, and exceptions to the warrant requirement apply, including that Plaintiffs consented and are free to opt out at any time.
4. Plaintiffs' healthcare providers are not state actors, so even if the providers failed to properly obtain informed consent from Plaintiffs, the State Defendants are not the appropriate parties from whom to seek relief.
5. Plaintiffs do not meet the factors for injunctive relief, and this Court should decline to exercise its jurisdiction to grant the requested declaratory relief.
6. Pursuant to E.D. Mich. LR 7.1(a), despite reasonable efforts by telephone call to Plaintiffs' counsel on March 29, 2021, counsel for the State Defendants were unable to contact Plaintiffs' counsel to explain the nature of the motion and its legal basis and therefore concurrence in this motion was not obtained.

WHEREFORE, for the reasons set forth in this motion and the attached brief, there is no genuine dispute as to any material fact, and the State Defendants are entitled to judgment as a matter of law. Therefore, the State Defendants ask this Court to grant its motion under Rule 56 and grant summary judgment in favor of Defendants.

Dana Nessel
Attorney General

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Dated: April 5, 2021

**CERTIFICATE OF SERVICE (E-FILE)**

I hereby certify that on April 5, 2021, I electronically filed the above document(s) with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

*/s/Aaron W. Levin*
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**BRIEF IN SUPPORT OF STATE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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## CONCISE STATEMENT OF ISSUES PRESENTED

1. Plaintiffs have either affirmatively consented to the availability of their children's dried blood spots for research uses or chosen not to have the dried blood spots destroyed. In either case, the State Defendants are entitled to judgment as a matter of law because they have at all times acted according to Plaintiffs' expressed directives.

2. Plaintiffs do not have an absolute right to direct their children's medical care; it is well-established that the State can intervene to protect the public health. To the extent Plaintiffs' consent is not dispositive, the retention and possible use of dried blood spots for research purposes (1) has not infringed Plaintiffs' ability to direct their children's medical care and (2) is narrowly tailored to further a compelling government interest.

3. There is no Fourth Amendment violation because government-based medical procedures conducted for purely medical purposes are not searches. Even if retention of dried blood spots does constitute a search or seizure, it is not unreasonable because three exceptions to the warrant requirement apply: Plaintiffs have consented to it, Plaintiffs are free to opt out at any time, and special needs make the warrant requirement impracticable.

4. There is no genuine dispute of material fact as to whether Plaintiffs provided informed consent to the retention of their dried blood spots because Plaintiffs' medical care providers are not state actors. Even if Plaintiffs' medical care providers failed to obtain consent properly, the State Defendants are not the appropriate parties from whom relief should be sought.

5. Plaintiffs have failed to present any material fact supporting the elements of a conspiracy.

6. The unconstitutional harm Plaintiffs allege will not recur and cause an injury specific to them, and the injunctive relief factors also weigh in the State Defendants' favor. The *Grand Trunk* factors for declaratory relief likewise weigh in the State Defendants' favor. Plaintiffs are not entitled to injunctive relief, and this Court should decline to issue declaratory relief.

## CONTROLLING OR MOST APPROPRIATE AUTHORITY

*Authority*:

- Fed. R. Civ. P. 56
- *Moldowan v. City of Warren*, 578 F.3d 351 (6th Cir. 2009)
- *Kanuszewski v. Michigan Dep't of Health & Human Servs.*, 927 F.3d 396 (6th Cir. 2019)
- *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200 (1995)
- *McKinstry v. Valley Obstetrics-Gynecology Clinic, P.C.*, 405 N.W.2d 88 (Mich. 1987)
- *Stout v. J.D. Byrider*, 228 F.3d 709 (6th Cir. 2000)
- *Carrigg v. Gen. R.V. Ctr., Inc.*, 421 F. Supp. 3d 480 (E.D. Mich. 2019)
- *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
- *Oliver v. United States*, 466 U.S. 170 (1984)
- *United States v. Carter*, 378 F.3d 584 (6th Cir. 2004)
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- *Grand Trunk W. R. Co. v. Consol. Rail Corp.*, 746 F.2d 323, 325 (6th Cir. 1984)

## INTRODUCTION

The State Defendants are not responsible for Plaintiffs' inaction. Plaintiffs authorized the State to make seven of their children's residual dried blood spots (DBS) available for research use. At all times, Plaintiffs had the ability to change the uses for which all of the DBS are authorized, or to have DBS returned or destroyed. Plaintiffs' choice not to do so is not a deprivation of any constitutional right.

Michigan law mandates taking newborn blood samples, testing them for disorders such as sickle cell anemia, phenylketonuria, and hypothyroidism, and storing them for quality-control and approved medical research. Plaintiffs concede that this program is "a noble public policy idea." (1st Am. Compl. ¶ 2, ECF No. 26, PageID.301.) Parents can direct that their child's DBS be returned or destroyed entirely once newborn screening is completed, or that they be stored but not used for research—options that have been presented to Plaintiffs multiple times, but that Plaintiffs have not availed themselves of.

Nevertheless, there are no injuries, constitutional or otherwise, from retention and possible use of Plaintiffs' dried blood spots. The DBS have not been used contrary to Plaintiffs' expressed directives—in fact,

Plaintiffs' DBS have not been used at all. Plaintiffs concede that retention of their dried blood spots has not impaired their ability to make medical decisions for their children—the alleged injury under the Fourteenth Amendment. And to the extent retention might implicate that right, the program is narrowly tailored to further a compelling government interest, *i.e.*, the early detection, treatment, and prevention of childhood disease. Retention of DBS is also not a search or seizure under the Fourth Amendment because it has no law enforcement purpose, and to the extent that it is a search or seizure it is reasonable because exceptions to the warrant requirement apply, including Plaintiffs' consent and freedom to opt out at any time.

Further, even if Plaintiffs' healthcare providers failed to properly obtain consent, those providers are not state actors. Thus, the State Defendants are not the appropriate defendants. Plaintiffs have also failed to raise any material fact evidencing a conspiracy. Finally, they are not entitled to injunctive or declaratory relief.

## STATEMENT OF FACTS

### A. Factual background

The Michigan newborn screening program screens for (and provides follow-up and referral for medical management of infants with) certain rare, insidious medical disorders that can result in serious disability or death.[1] (*LaPorte v. Gordon et al.*,[2] Opinion & Order, 1:20-cv-10089 ECF No. 29, PageID.442; MDHHS Michigan Newborn Screening Questions and Answers Ex. 1 at 1, available at www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916-233319--,00.html (last accessed April 2, 2021).) *See also* Mich. Comp. Laws § 333.5431.

Michigan began its newborn screening program in 1965. The Michigan Legislature passed, and the Governor signed, 1965 PA 119, now codified at Mich. Comp. Laws § 333.5431, which required that

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[1] The Newborn Screening Clearinghouse, housed on the website BabysFirstTest®, is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services and provides valuable information to the public about newborn screening performed across the country. Available at www.babysfirsttest.org/ (last accessed April 2, 2021).

[2] *LaPorte v. Gordon* was consolidated with this case on April 28, 2020, prior to its voluntary dismissal. (Order Consolidating *LaPorte v. Gordon* with *Kanuszewski v. MDHHS*, ECF No. 104, PageID.1520.)

health professionals in charge of the care of a newborn test for the disorder phenylketonuria, a genetic disorder that can cause intellectual disability, seizure, behavioral problems, and other mental disorders. Michigan's newborn screening evolved, and by 1978 the statute was amended to allow additional diseases to be tested and to provide that a person who violates the statute's newborn screening requirements is guilty of a misdemeanor.[3] (*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.442; Ex. 1 at 1.) *See also* Mich. Comp. Laws § 333.5431.

To ensure the quality, consistency, and efficiency of newborn screening through centralized screening, the statute was amended in 1987 to permit the Michigan Department of Health and Human Services ("MDHHS") to require that newborn screening be performed at

[3] Numerous new disorders have been added to the newborn screening blood spot panel, increasing from one in 1965 to five in 1993 to 56 today (plus hearing and critical congenital heart disease screened through other means). (https://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916-233939--,00.html (last accessed April 2, 2021).) Disorders are added through operation of the Newborn Screening Quality Assurance Advisory Committee, established in 2006 and codified at Mich. Comp. Laws § 333.5430. This committee includes representatives of Michigan's medical associations, hospitals, MDHHS, and the public.

the MDHHS Laboratory.[4] (*See LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.442-43; Ex. 1 at 1.) *See also* Mich. Comp. Laws § 333.5431(2).) In 2000, the statute was again amended to, among other things, expressly exempt newborn screening testing from informed consent requirements and require MDHHS to: (1) develop a schedule for the retention and disposal of residual dried blood spots ("DBS") after newborn screening is completed; (2) make the DBS available for medical research during the established retention period; and (3) publish a pamphlet explaining the newborn screening program and statutory requirements, including the retention and disposal period for DBS and that they may be used for medical research. Mich. Comp. Laws § 333.5431(2), (7), and (8).

Pursuant to Mich. Comp. Laws § 333.5431, Michigan's newborn screening program uses five or six DBS collected on a filter paper collection card. (*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29,

[4] The MDHHS Laboratory is accredited by the College of American Pathologists and the Centers for Medicare & Medicaid Services and bases testing protocols on the Clinical and Laboratory Standards Institute's Guidelines for Health Care Excellence. *See* www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103-14582--,00.html (last accessed April 2, 2021).

PageID.441; Ex. 1 at 2; MDHHS Michigan Newborn Screening Pamphlet Ex. 2 at 2,[5] available at www.michigan.gov//mdhhs/0,5885,7-339-73971_4911_4916-233588--,00.html (last accessed April 2, 2021); MDHHS APF-111 – Newborn Screening Specimens Ex. 3 at 1.) The collected DBS are then transported from Michigan birthing sites (*e.g.*, hospitals, home births) to the MDHHS Laboratory, where the specimens are screened for 56 disorders; MDHHS newborn screening follow-up staff then inform healthcare providers if a disorder is suspected and ensure that infants are connected to care. (*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.441; Ex. 1 at 2.) Every year more than 250 infants (roughly one in 400 to 500 births) are found to have a disorder. (Ex. 1 at 1.) Nationally, about 12,500 newborns are diagnosed with a condition identified through newborn screening annually. (*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.441.) Since the newborn screening program began in 1965, it has identified more than 7,200 Michigan infants with disorders. (*Id.*)

[5] Exhibit 2 is the current version of the pamphlet. Older versions have been attached for reference to evidence that there was a pamphlet in use at the time each of the Plaintiff-Children was born, though some may reference policies that are no longer in use. (Historical Newborn Screening Pamphlets Ex. 31.)

After newborn screening is completed, parents or legal guardians may require MDHHS to destroy their child's DBS stored pursuant to Mich. Comp. Laws § 333.5431. (*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.442-44; Ex. 3 at 1; MDHHS Residual Newborn Screening Blood Spot Directive Ex. 4, available at www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246-244016--,00.html (last accessed April 2, 2021).[6]) Parents or legal guardians may also direct that the DBS be returned to them. (Lyon-Callo Dep Ex. 23 at 67.) If parents or guardians do not submit a directive prior to the individual from whom the DBS were collected reaching age 18, the individual must make the request and provide the requisite documentation. (Ex. 3 at 1; Ex. 4.) Directives may be submitted to MDHHS by mail, fax, or email. (Ex. 4.) This information is provided to parents at the time of newborn screening by their

[6] Exhibit 4 is the current version of the directive form. There are two historical versions—one to opt out of research and one to request destruction. (Historical Directives to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses Ex. 5; Historical Directives to Destroy Newborn Screening Blood Specimen Ex. 6.) The two forms have now been combined into one document. (Ex. 4.)

healthcare provider, Mich. Comp. Laws § 333.5431, and the directive is available from MDHHS and online.

Absent a destruction request, MDHHS stores DBS for potential authorized uses. Authorized uses are limited by medical research project designation, *see* Mich. Comp. Laws §§ 333.2631-2638, to newborn screening quality improvement and test development, approved research projects, parent-directed use, and crime-victim identification (the only approved law-enforcement use). (Ex. 3 at 1; MDHHS APF 114 – Guidelines for Research Use of Dried Blood Spots Ex. 7 at 2-5; MDHHS Application for Designation as a Medical Research Project & Approval Letter Ex. 8 at 2; Seeterlin Decl. Ex. 21 at 2-6.) Recognizing DBS's public health research value, the Legislature amended § 333.5431 in 2000 to mandate that MDHHS also permit medical research using de-identified DBS. Mich. Comp. Laws § 333.5431(7)(b). MDHHS created a program, the Michigan BioTrust for Health ("BioTrust"), to facilitate research access to stored DBS.[7]

[7] A summary of the research requesting blood spots from Michigan is available online. (Research Use of Michigan's Residual Newborn Screening Blood Spots, available at https://www.michigan.gov/documents/mdch/Dried_Blood_Spot_Research_Table_Public_Report_347898_7.pdf, last accessed April 2, 2021.)

(*LaPorte*, Op. & Order, 1:20-cv-10089 ECF No. 29, PageID.445.) DBS are stored under the retention schedule that § 333.5431(7) requires MDHHS to establish— currently 35 years for DBS and demographic data and 22 years for screening data.[8] (Ex. 21 at 3.)

One of the six DBS is securely stored at the MDHHS Laboratory for parental use, if needed (*e.g.*, future disease diagnosis, deceased child identification, autopsy); the other five are likewise de-identified, assigned the same anonymous numeric code, and stored at a secure site where only authorized individuals have access to the de-identified DBS, the Michigan Neonatal Biobank (Biobank) in Detroit. (Ex. 9 at 1-2; MDHHS BioTrust Frequently Asked Questions Ex. 10 at 1, available at www.michigan.gov//mdhhs/0,5885,7-339-73971_4911_4916-233588--,00.html (last accessed April 2, 2021).) MDHHS maintains the sole link that would enable re-coding to identify a stored DBS; Biobank cannot access this identifiable information. (Ex. 5 at 4; Ex. 6 at 3; Ex. 10 at 1.)

[8] While MDHHS policies allow for DBS to be retained for up to 100 years, (Ex. 7 at 5; Ex. 3 at 1; MDHHS After Newborn Screening – Your Baby's Blood Spots Ex. 9 at 2, available at www.michigan.gov//mdhhs/0,5885,7-339-73971_4911_4916-233588--,00.html (last accessed April 2, 2021),) the current retention schedule is only 35 years.

MDHHS retains qualified ownership of DBS while in storage, meaning only MDHHS has the power to direct the use of DBS; the Biobank's role is merely to maintain the DBS and to use them consistent with MDHHS's directives. MDHHS may release part, or all, of the de-identified DBS for three types of uses: quality assurance essential to continuation of the newborn screening program; research use through the BioTrust program; and parent-directed use or destruction. (*See* Ex. 3 at 1; Ex. 9 at 2; Lyon-Callo Dep. Ex. 23 at 66.)

In furtherance of Michigan's commitment to providing parental decision-making opportunities, MDHHS in 2010 implemented an "opt-in" consent process through the BioTrust program; since May 1, 2010, a parent or legal guardian directs—at the time of collection—whether their newborn's stored DBS can be used for research, and may change this decision later by completing the directive form. (Ex. 9 at 1-2; Ex. 10 at 2; MDHHS Michigan BioTrust for Health – Consent Options Ex. 11 at 1-2, available at www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246-244016--,00.html (last accessed April 2, 2021); BioTrust Research Consent Form Ex. 12, available at www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246-

244016--,00.html (last accessed April 2, 2021).) Accordingly, stored DBS for children born on or after May 1, 2010 may be used for deidentified research through the BioTrust only if a parent or legal guardian returns a signed consent form allowing it.[9] (*Id.*) Parents are also expressly informed that their child's DBS will be stored even if they say "no" to research unless they complete the directive form to destroy. (*Id.*) For stored DBS of children born before May 1, 2010, their de-identified DBS are available for health research under a waiver of the informed consent requirement granted by the MDHHS Institutional Review Board. (Institutional Review Board Approval Forms for Michigan Neonatal Biobank Ex. 13; 45 C.F.R. § 46.116 effective June 23, 2005 to July 18, 2018, Ex. 32.[10]) Individuals whose DBS are included in this group can also "opt out" at any time by requesting their DBS be returned, destroyed entirely, or stored but not used for research. (Ex. 9 at 1-2; Ex. 10 at 2; Ex. 11 at 1-2; Ex. 12; Ex. 23 at 66.)

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[9] Identified research using DBS can only be performed if parents or guardians provide study-specific consent, which is sought on a case-by-case basis.

[10] Because deidentified research under the BioTrust was approved prior to January 21, 2019, it is subject to the pre-2018 Common Rule. 45 C.F.R. § 46.101(l)(3). The current version also allows for waivers of informed consent under certain circumstances. 45 C.F.R. § 46.116(e).

### B. Procedural history

On February 8, 2018, Plaintiffs filed their initial complaint. (Compl., ECF No. 1, PageID.1.) Plaintiffs filed a "corrected complaint" on February 17, 2018, which alleged that the newborn screening program's heel stick, screening, and storage violated their Fourth and Fourteenth Amendment rights. (Corrected Compl., ECF No. 3, PageID.42.)

On April 17, 2018, the State Defendants filed a motion to dismiss. (Mot. to Dismiss, ECF No. 21, PageID.171.) This motion argued, among other things, that Plaintiffs' corrected complaint should be dismissed for failure to state a claim under Rule 12(b)(6), lack of standing under Rule 12(b)(1), and governmental immunity.

Rather than respond to the State Defendants' motion, Plaintiffs filed a First Amended Complaint on April 30, 2018. (1st Am. Compl., ECF No. 26, PageID.300.) The First Amended Complaint raised substantially the same issues as the corrected Complaint.

On May 29, 2018, the State Defendants filed a Motion to Dismiss the First Amended Complaint. (Mot. to Dismiss 1st Am. Compl., ECF No. 32, PageID.477.) The State Defendants reiterated that Plaintiffs

had failed to state a claim, failed to establish standing, and failed to plead in avoidance of governmental immunity.

On August 8, 2018, this Court issued an Order granting the State Defendants' motion to dismiss and dismissed Plaintiffs' claims with prejudice. (8/8/18 Order, ECF No. 50, PageID.825.)

Plaintiffs appealed. The Sixth Circuit held, in short, that Plaintiffs' claims regarding the initial heel stick and screening were properly dismissed based on standing, qualified or sovereign immunity, or for failure on the merits. *Kanuszewski v. Michigan Dep't of Health & Human Servs.*, 927 F.3d 396, 412, 414, 416, 423 (6th Cir. 2019). The Court remanded Plaintiffs' claims regarding retention and possible use of DBS to this Court for further proceedings. *Id.* at 426.

### C. Plaintiffs' retained DBS and participation in the BioTrust program

In this case, there are four Plaintiff-Parents representing their collective nine children. Plaintiffs Adam and Ashley Kanuszewski bring this action on behalf of Plaintiff-Children D.W.L,[11] born January 17,

[11] Plaintiff Adam Kanuszewski advised in his deposition that he is not D.W.L.'s biological father and has not adopted D.W.L. (Adam Kanuszewski Dep. Ex. 24 at 21.) No other alleged fact or record

2008; R.F.K., born April 22, 2013; and C.K.K., born February 10, 2016. (1st Am. Compl., R. 26, ¶ 16, PageID.304.) Plaintiff Shannon LaPorte brings this action on behalf of Plaintiff-Children M.T.L., born October 19, 2008; and E.M.O., born February 6, 2017. (*Id.* ¶ 17.) Plaintiff Lynette Wiegand brings this action on behalf of Plaintiff-Children L.R.W., born November 21, 2011; C.J.W., born July 17, 2013; H.J.W., born December 24, 2014; and M.L.W., born January 30, 2017. (*Id.* ¶ 18.)

Plaintiff Ashley Kanuszewski signed an authorization allowing the retained DBS for R.F.K. and C.K.K. to be used for health research on the date each child was born. (Michigan BioTrust for Health blood spot directive dated April 22, 2013 Ex. 14; Michigan BioTrust for Health blood spot directive dated February 10, 2016 Ex. 15.) Plaintiff Shannon LaPorte signed, on the date of E.M.O.'s birth, an authorization that did not allow for the DBS retained from E.M.O. to be used for health research but indicated the spots would be stored and may be used to help ensure the newborn screening program detects those at risk, and that advised LaPorte that if she wanted the blood spots to be

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evidence establishes his guardianship over D.W.L. Therefore, it appears he does not have the legal authority to assert claims on behalf of D.W.L.

destroyed she must contact MDHHS. (Michigan BioTrust for Health blood spot directive dated February 6, 2017 Ex. 16.) Plaintiff Lynette Wiegand signed, on either the day of or the day following her children's birth, an authorization allowing the retained DBS for L.R.W., C.J.W., and H.J.W. to be used for health research, and she signed an authorization for M.L.W. that did not allow the retained DBS to be used for health research but indicated that the spots will be stored and may be used to help ensure the newborn screening program detects those at risk, and advised that if she wanted the blood spots to be destroyed she must contact MDHHS. (Michigan BioTrust for Health blood spot directive dated November 22, 2011 Ex. 17; Michigan BioTrust for Health blood spot directive dated July 18, 2013 Ex. 18; Michigan BioTrust for Health blood spot directive dated December 25, 2014 Ex. 19; Michigan BioTrust for Health blood spot directive dated January 30, 2017 Ex. 20.) Plaintiff-Children D.W.L. and M.T.L., who were born prior to 2010, do not have signed directives on file because of the statutory waiver of the consent requirement for newborn screening and the policy waiving the informed consent requirement for use of DBS obtained before May 2010 for research purposes. (Ex. 13; Ex. 32.) Plaintiff-

Parents have not requested destruction or return of their children's DBS. (Kleyn Decl. Ex. 22 at 3.) None of the Plaintiff-Children's DBS have been used for any purpose after newborn screening was completed. (Ex. 21 at 6; Ex. 22 at 3.)

## STANDARD OF REVIEW

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. "[W]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009) (citations omitted).

## ARGUMENT

### I. Defendants are entitled to judgment as a matter of law.

At the outset, it is important to consider the narrow focus of the claims remaining in this case. This is not a class action, and Plaintiffs do not seek statewide relief. (Resp. to State Defendants' Mot. to Dismiss 1st Am. Compl., ECF No. 45, PageID.714) ("'[S]tatewide relief' is not demanded. . . The Plaintiffs' claims rest solely on what happened and is

happening to them, and not any third parties.") Therefore, the remaining claims focus on only the retention of the DBS for the nine Plaintiff-Children in this case, and Plaintiffs may only seek prospective relief. *Kanuszewski*, 927 F.3d 396 at 417-418, 424. Further, none of the DBS at issue have been used for any purpose, either by MDHHS or a third party (Ex. 21 at 6; Ex. 22 at 3.)

Because Plaintiffs have either affirmatively consented to the availability of their DBS for deidentified research or chosen to not have their children's DBS destroyed or returned—options that have been available at all times before and during this litigation—and because retention of DBS has not interfered with any Plaintiffs' ability to direct their children's medical care and is not an unreasonable search or seizure, Defendants are entitled to judgment as a matter of law.

### A. Plaintiffs have affirmatively consented or continue to allow participation in the BioTrust program.

MDHHS has not used any DBS contrary to the expressed wishes of the parents (Ex. 14; Ex. 15; Ex. 16; Ex. 17; Ex. 18; Ex. 19; Ex. 20; Ex. 21 at 6; Ex. 22 at 3), and Plaintiffs have no evidence suggesting otherwise. (Ex. 24 at 6, 11, 13; Ashley Kanuszewski Dep. Ex. 25 at 7,

10, 16-17; LaPorte Dep. Ex. 26 at 12, 14, 17; Wiegand Dep. Ex. 27 at 27). Further, Plaintiffs do not dispute that they signed the directives. (Ex. 24 at 10; Ex. 25 at 10; Ex. 26 at 11, 14; Ex. 27 at 18-21.) At all times, Plaintiffs were able to direct the retention and authorized uses of their children's DBS, including having the DBS destroyed or returned. They have elected not to do so. This information is available to the public, but Plaintiffs concede they have never looked for it or contacted MDHHS to learn more. (Ex 24 at 6; Ex. 25 at 6, 12, 30; Ex. 26 at 28-29; Ex. 27 at 7-8.) Plaintiff Wiegand even acknowledged that she may have been given this information prior to the birth of one of her children and chose not to read it. (*See* Ex. 27 at 31.)

Michigan law "presumes that one who signs a written agreement knows the nature of the instrument so executed and understands its contents. The purpose of this rule is well recognized—to preserve the integrity and stability of written instruments." *McKinstry v. Valley Obstetrics-Gynecology Clinic, P.C.*, 405 N.W.2d 88, 96 (Mich. 1987) (citations omitted); *see Stout v. J.D. Byrider*, 228 F.3d 709, 715 (6th Cir. 2000) ("This Court applies the cardinal rule that, in the absence of fraud or wilful deceit, one who signs a contract which he has had an

opportunity to read and understand, is bound by its provisions." (quotation omitted)).

To the extent Plaintiffs argue that they were not provided adequate information at the time their children were born, this is directly contradicted by the signed directives, which are the best evidence of what Plaintiffs knew and intended at the time the documents were signed. If this Court considers the opinion of Plaintiffs' expert,[12] Dr. Eisenhauer, it is worth noting that, in the only published study she has performed regarding consent for the BioTrust program, she found in her limited sample that all of the mothers—even those Dr. Eisenhauer concluded were not sufficiently informed by their medical care providers about possible research uses for DBS—made choices consistent with their attitudes about the research. (Elizabeth R. Eisenhauer, *Mothers' Decisions About Donating Newborns' Blood Spots for Research*, 33 J. Perinat. Neonat. Nurs. 361, 366 (2019) Ex 28. ("No choice was inconsistent with the stated attitudes about the research.")) Regardless, the directives explicitly reference additional information

[12] The State Defendants' motion to exclude expert testimony has not yet been resolved at the time of filing this motion.

that was provided at the same time as the directive. (Ex. 14; Ex. 18.) Plaintiffs had a duty to read the directives before signing, and failure to do so is not a defense. *Carrigg v. Gen. R.V. Ctr., Inc.*, 421 F. Supp. 3d 480, 490-91 (E.D. Mich. 2019) (citing *Montgomery v. Fid. & Guar. Life Ins. Co.*, 713 N.W.2d 801, 804 (Mich. Ct. App. 2005); *Scholz v. Montgomery Ward & Co., Inc.*, 468 N.W.2d 845, 848 (Mich. 1991).) Thus, summary judgment is appropriate for Plaintiffs' claims regarding DBS retained from R.F.K., C.K.K., E.M.O., L.R.W., C.J.W., H.J.W., and M.L.W.

The same result is true for D.W.L. and M.T.L., for whom no directives were signed under the policy that does not require informed consent for the BioTrust program for retained DBS obtained before 2010. (Ex. 13; Ex. 32 at 3.) Even if Plaintiff Ashley Kanuszewski was not informed by her healthcare professional at the time of D.W.L.'s birth—and the pamphlet in use at the time of D.W.L.'s birth noted that DBS are retained—she has been on notice that DBS are retained and made available for research since at least April 22, 2013, when she signed an authorization allowing R.F.K.'s DBS to be available for research. (Ex. 14; Ex. 31 at 12.) Similarly, even if Plaintiff LaPorte was

not informed by her healthcare professional at the time of M.T.L.'s birth—and the pamphlet in use at the time also noted DBS are retained—she has been on notice that DBS are retained and made available for research since at least February 6, 2017, when she signed a directive indicating that E.M.O.'s blood spots may not be used for health research. (Ex. 16; Ex. 31 at 10.) These Plaintiffs sat on their hands for approximately four and eight years, respectively, and never expressed to MDHHS that the use of D.W.L.'s and M.T.L.'s DBS for deidentified research was against their wishes.

Nevertheless, the availability of D.W.L.'s and M.T.L.'s DBS for deidentified research, without consent, is consistent with federal law under a waiver of informed consent. Research through the BioTrust is conducted in accordance with the pre-2018 Common Rule. (Ex. 32.) The Common Rule acknowledges that requirements for informed consent are not appropriate for all forms of research that may be subject to the Common Rule regulations. As such, the Common Rule includes appropriately limited provisions allowing for waivers or alterations of informed consent requirements. (*Id.* at 3.)

In 2010, when MDHHS adopted the current opt-in policy regarding deidentified research, many DBS were already being retained for newborn screening purposes (quality improvement, quality assurance, parent-directed use, etc. (Ex. 21 at 2-6.).) These DBS held great potential value to public health research, but it would have been, and still is, impracticable to seek consent from each individual from whom DBS were already held. The then-Michigan Department of Community Health Institutional Review Board (IRB) approved a procedure waiving informed consent for DBS obtained pre-2010 because (1) the research involves no more than minimal risk—risk is minimized by using already-held specimens, a widely accepted strategy that is not controversial; (2) the waiver does not adversely affect the rights and welfare of the individual because it does not require active participation and is anonymous; (3) the research could not practicably done without the waiver; and (4) individuals are provided with additional pertinent information when appropriate. (Ex. 32 at 3; Ex. 13.) Research done with this kind of waiver is commonplace nationally, and a finding invalidating waivers such as this could devastate legally and ethically

sound research being done throughout the country, most of it unrelated to newborn screening.

Plaintiffs' failure to exercise their ability to remove their DBS from availability for anonymous research, combined with the consent for deidentified research provided for their other children's DBS, demonstrates that MDHHS has never used Plaintiffs' DBS contrary to their expressed wishes. Regardless, these DBS have not been used for post-screening purposes.

### B. Participation in the BioTrust program has not infringed any Plaintiff's ability to direct his or her children's medical care.

Plaintiffs concede that the State retaining their children's DBS has not impaired their ability to direct their children's medical care. (Ex. 24 at 19-20; Ex. 25 at 17; Ex. 27 at 31.) And to the extent the BioTrust program implicates Plaintiff-Parents' ability to direct their children's medical care, as argued above, Plaintiff-Parents directed MDHHS to make most of the DBS at issue available for research. Thus, Plaintiffs' rights under the Fourteenth Amendment to direct their children's medical care has not been violated, and Defendants are entitled to summary judgment.

Alternatively, although Plaintiff-Parents have a fundamental right to direct their children's medical care, "[t]his does not mean that parents' control over their children is without limit . . . . Indeed, limitations on parents' control over their children are particularly salient in the context of medical treatment." *Kanuszewski*, 927 F.3d at 419 (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905)). Plaintiffs' argument that retention of DBS violates their Fourteenth Amendment rights to direct their children's medical care is based only on the existence of such a right; Plaintiffs argue that this right is absolute. But that is wrong. "A parent's right to control the custody and care of her children is not absolute, as the State has a legitimate interest in protecting 'the moral, emotional, mental, and physical welfare of the minor.'" *In re Sanders*, 852 N.W.2d 524, 532 (Mich. 2014) (quoting *Stanley v. Illinois*, 405 U.S. 645, 652 (1972)). "Supreme Court precedent recognizes 'two competing values of equal worth: the right of parents to parent and the right of children to safety.' " (*LaPorte*, Op. & Order, ECF No. 29, PageID.457 (quoting *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1140 (D. Neb. 2006)).

Nevertheless, because the newborn screening program is subject to strict scrutiny (*Id.* at PageID.456-57), the retention of DBS is also likely subject to strict scrutiny and will be upheld if it is narrowly tailored to a compelling government interest. However, "[s]trict scrutiny is not 'strict in theory, but fatal in fact.' " *Johnson v. California*, 543 U.S. 499, 514 (2005) (quoting *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 237 (1995)). "The fact that strict scrutiny applies 'says nothing about the ultimate validity of any particular law; that determination is the job of the court applying strict scrutiny.' " *Id.* at 515 (quoting *Adarand*, 515 U.S. at 237).

The Sixth Circuit recognized that there is a compelling governmental interest in the newborn screening program:

> The state's interest in preserving the welfare of children is at its zenith when the life of the child is at stake, and in such circumstances the state in its role of *parens patriae* may subordinate the interest of the child's parents to its own interest in keeping the child alive.

*Kanuszewski*, 927 F.3d at 419 (citing *Schall v. Martin*, 467 U.S. 253, 265 (1984)). Although the Sixth Circuit declined to examine the merits of a claim alleging violation of a parent's substantive due process rights based on the newborn screening program, it noted that

> [a] program to screen children for life-threatening diseases at birth may be an example of a state's proper exercise of its *parens-patriae* role, provided that the state operates the program for purely benevolent motives. It may well be that the NSP [newborn screening program] would survive strict scrutiny to the extent that it involves drawing the children's blood and screening for life-threatening diseases.

*Id.* at 419–20 (citing *Jacobson*, 197 U.S. at 38; *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944)).

Wholly separate from the BioTrust consent process, all residual DBS may be used by MDHHS for limited purposes necessary to maintain the ongoing function of the newborn screening system. Retention may benefit the individual from whom the DBS were obtained (e.g., DBS are sometimes used by physicians in diagnosing and treating other conditions), but of greater importance is the value to the public health in maintaining and expanding the newborn screening program, allowing for the identification and treatment of congenital disorders in all newborns.

Retained DBS are vital to maintaining an accurate and timely newborn screening program. (Ex. 21 at 2.) Newborn screening is not one test; after the hearing tests and critical congenital heart disease testing done at the time of birth, the newborn screening laboratory utilizes over

29 instruments over nine different testing areas to screen DBS. (*Id.* at 3-4.) The performance of each of these instruments must be verified prior to clinical use, which typically requires a minimum of 5,000 DBS, but can require more depending on the circumstances. (*Id.* at 3.) There are similar requirements for validating instruments' results and improving the accuracy of laboratory equipment. (*Id.* at 3-4) The newborn screening laboratory transitions to new testing equipment virtually every year. (*Id.* at 4.)

Through these testing areas, the newborn screening laboratory tests for the presence of analytes in the blood. Newborn screening is not diagnostic testing. (*Id.* at 4.) Rather, the tests screen the DBS to determine the amount of the screened-for analytes in the blood, and at certain quantities these analytes can be indicative of disease and follow-up testing or treatment will be recommended. No other data is tested for or retained. Retaining DBS is vital for determining the cutoffs used in screening. (*Id.* at 3-4.) Further, because some of the maladies screened for are quite rare, the pool of retained DBS must be very large; some disorders appear only once in ten years, yet the machinery must be maintained to ensure that when such a child is born, they are not

missed. (*Id.* at 4.) Retained DBS are also used for retesting to reduce the number of false negative results. (*Id.* at 4-5.) Because of the dire health outcomes that can result from false negative tests, the newborn screening program takes this responsibility very seriously. (*Id.*) Without retention of DBS, the newborn screening system could not function.

Retaining data is also necessary for the operation of the newborn screening program. Data is crucial for quality improvement, especially cutoff evaluations. (*Id.* at 5.) Having data over many years is important in order to have statistical confidence. (*Id.*) Demographic data is also important to ensure the correct DBS are retrieved in response to parent-driven requests, including sending DBS to a doctor's office to assist with diagnosis or treatment, research directed by a parent, and return or destruction of DBS. (*Id.* at 6.)

Because retention of DBS is necessary to ensure a robust, accurate, and effective newborn screening program, there is no question DBS are retained for a compelling government purpose.

In addition to furthering a compelling government purpose, retention of DBS is narrowly tailored. MDHHS accomplishes this in several ways. First, MDHHS obtains informed general consent for use

of DBS for purposes other than those necessary to keep the newborn screening program operational. Second, even with informed consent, DBS may only be used for anonymous research; that is, the DBS must be de-identified. Third, DBS may be destroyed or returned upon request at any time, and the uses for which retained DBS are authorized may be changed by a parent or legal guardian, or the individual from whom the DBS were obtained after they turn 18. These policies are entirely consistent with those advocated for by Professor Sonia Suter—Plaintiffs' expert witness. (Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 Minn. J.L. Sci. & Tech. 729, 765, 770, 773-74, 779, (2014) Ex. 29; Suter Dep. Ex. 33 at 12-16, 17-18, 24-25.) Thus, the scope of permissible uses for retained DBS is at all times under the direction of a parent, legal guardian, or the individual.

Further, retained DBS are stored in secured facilities and may only be used for purposes approved under the program's medical research project designation. *See* Mich. Comp. Laws §§ 333.2631-2638. Violations of the medical research project designation protections require termination of MDHHS employees and may bring criminal

liability. Mich. Comp. Laws § 333.3638. Approved purposes include only newborn screening quality improvement and test development, approved research projects, parent-directed use, and crime-victim identification. (Ex. 3 at 1; Ex. 7 at 2-5; Ex. 8 at 2.) Even these uses are subject to additional confidentiality protections; crime-victim identification requires a subpoena, parent-directed use requires proof of an individual's authority to direct the use, and research projects go through extensive review.

If retained DBS are authorized for research, they are also subject to additional privacy protections. MDHHS assigns each DBS a numeric code before possession of the DBS is transferred to the Biobank. The Biobank does not have access to any personally identifying information. This ensures anonymity. The Biobank also assigns an added numeric code before allowing MDHHS-approved researchers access to the DBS. (Yancey Dep. Ex. 30 at 13, 37-38.) The numeric code used by researchers is not the same as that assigned by MDHHS. Thus, neither the Biobank nor any approved third parties have access to the information necessary to identify any individual based on their DBS. And continuous involvement of the Community Values Advisory Board

and Scientific Advisory Board, together with required oversight, review, and approval by the MDHHS Institutional Review Board, ensures that any research use adheres strictly to federal and state laws and regulations governing human subject research. (Ex. 7; Ex. 13.) *See also, e.g.,* 45 C.F.R. § 46.101 *et seq*. These limitations and protections ensure confidentiality and choice for parents and individuals of age with regard to their retained DBS. Accordingly, the retention of DBS is narrowly tailored to achieve a compelling government interest, and defendants are entitled to summary judgment on Count I and Count II, which allege violations of the Fourteenth Amendment.

### C. Participation in the BioTrust program is not an unreasonable search or seizure.

The Fourth Amendment protects "the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures . . . ." *United States v. Jones*, 565 U.S. 400, 404 (2012). The touchstone of Fourth Amendment analysis is "whether a person has a constitutionally protected reasonable expectation of privacy." *Oliver v. United States*, 466 U.S. 170, 177 (1984) (quotations omitted).

"The [Fourth] Amendment does not protect the merely subjective expectations of privacy, but only those expectation[s] that society is prepared to recognize as reasonable." *Id.* And that right is personal and cannot be vicariously asserted. *Rakas v. Illinois*, 439 U.S. 128, 133–34 (1978) (citing *Brown v. United States*, 411 U.S. 223, 230 (1973)).

Plaintiffs assert that the retention of their DBS without a warrant is necessarily a Fourth Amendment violation. That misstates the law. As a threshold matter, the retention of DBS does not implicate the Fourth Amendment because it is done for purely medical purposes. Second, there are exceptions to the warrant requirement—including consent—that apply in this case.

### 1. Retaining DBS for medical purposes does not constitute a search or seizure.

Many courts, including the Sixth Circuit, recognize that procedures undertaken for "purely medical reasons" may not be Fourth Amendment searches.[13] *See Hearring v. Sliwowski*, 712 F.3d 275, 281

[13] This Court previously found that the heel stick done for newborn screening is a search. (ECF No. 50, PageID.841.) The State Defendants assert this argument both because retention is distinct from the initial test, and in order to preserve this argument in the event of an appeal.

(6th Cir. 2013) (holding that Fourth Amendment does not apply to visual inspection for medical purposes); *Peete v. Metro. Gov't of Nashville & Davidson Cty.*, 486 F.3d 217, 222 (6th Cir. 2007) (holding that paramedics who "were not acting to enforce the law, deter or incarcerate" did not breach the Fourth Amendment); *United States v. Attson*, 900 F. 2d 1427, 1433 (9th Cir. 1990) (holding that no Fourth Amendment search occurred where procedures undertaken for "purely medical reasons"). This issue has not been settled in this Circuit. *Kanuszewski*, 927 F.3d at 423. Because the most significant reason DBS are retained—and the only reason DBS are retained and used without consent—is to ensure the continued efficacy of the newborn screening program, retention is primarily for medical purposes and does not implicate the Fourth Amendment.

### 2. Alternatively, retention of DBS is reasonable under the Fourth Amendment.

Nevertheless, even if retention of DBS constitutes a search or seizure as contemplated by the Fourth Amendment, there can be no doubt that it reasonable given the benefit to, and goals of, the newborn screening program. Warrantless searches or seizures are reasonable

when certain exceptions apply. *Missouri v. McNeely*, 569 U.S. 141, 148 (2013). To the extent the Fourth Amendment is implicated, multiple exceptions apply to the newborn screening program. First, Plaintiffs consented, as described above, to their children's DBS being available for research, which necessarily requires retention. Consent obviates the warrant requirement. *Florida v. Bostick*, 501 U.S. 429, 439 (1991) (Fourth Amendment "does not proscribe voluntary cooperation"); *Schneckloth v. Bustamonte*, 412 U.S. 218, 219 (1973); *United States v. Carter*, 378 F.3d 584, 587 (6th Cir. 2004) ("It is well-settled that a person may waive his Fourth Amendment rights by consenting to a search."). Further, if the target of the alleged search or seizure retains the ability to stop that governmental activity, that activity was reasonable. *United States v. Mendenhall*, 446 U.S. 544, 554 (1980) ("As long as the person . . . remains free to . . . walk away, there has been no intrusion upon that person's liberty or privacy as would under the Constitution require some particularized and objective justification.") Plaintiffs have at all times been free to change their minds and have the DBS at issue removed from MDHHS custody. Because this information is described on the signed directive, and available online or

by contacting MDHHS, a reasonable person would not believe they are not free to opt out of retention. Thus, MDHHS did not violate the Fourth Amendment. *See id.*

Second, notwithstanding Plaintiffs' consent, the special needs doctrine applies "when special needs, beyond the normal need for law enforcement, make the warrant and probable-cause requirement impracticable." *Bd. of Educ. of Indep. Sch. Dist. No. 92 of Pottawatomie Cty. v. Earls*, 536 U.S. 822, 843 (2002). In such cases, courts are tasked with balancing the nature of the intrusion on the individual's privacy against the promotion of legitimate government interests. *Id.* at 829.

In this case, the exercise of government authority is distinct from law enforcement: there is no consideration of wrongdoing, no possibility of detecting criminal conduct, and the program is designed to ensure public safety by protecting the health and safety of infants. Further, requiring a warrant for DBS every time equipment is calibrated or anonymous research is requested would be an impossible standard given the lack of a criminal purpose—there would never be probable cause of wrongdoing. Even assuming some different warrant requirement, such a step would cause significant delay and risk to the

health of Michigan children, as well as place a significant burden on the legal system. *See Camara v. Mun. Ct. of City & Cty. of San Francisco*, 387 U.S. 523, 539 (1967) (holding the warrant requirement for administrative searches is not "intended to foreclose prompt inspections, even without a warrant, that the law has traditionally upheld in emergency situations," including mandatory vaccinations and health quarantines.) Because retention is done to ensure the public health through effective newborn screening; with notice, consent for research, and the ability to remove a child's, or one's own, DBS at any time; and because of the risk to public safety and the lack of a purpose relating to the violation of a criminal statute, retention of DBS is reasonable and does not violate the Fourth Amendment. Therefore, Defendants are entitled to summary judgment on Count III, Count IV, and Count V.

### D. Plaintiffs' healthcare providers are not state actors.

Notwithstanding the above, even if this Court determines that there is a question of fact regarding what Plaintiffs knew at the time they authorized the use of their children's DBS, it should nevertheless

enter summary judgment because the State Defendants are not the responsible parties.

Mich. Comp. Laws § 333.5431 requires "[a] health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant" is responsible for obtaining DBS consistent with MDHHS's retention schedule. Mich. Comp. Laws § 333.5431(1), (7). This includes providing the directive regarding retention and use of DBS in the BioTrust program and the additional information referred to in the directive. A health professional who fails to do so is "is guilty of a misdemeanor." Mich. Comp. Laws § 333.5431(5).

To the extent Plaintiffs argue they were not provided the directive and the additional information, or that their signatures or the information provided were somehow deficient, they have not named the proper defendants. "[T]he mere fact that a business is subject to state regulation does not by itself convert its action into that of the State for purposes of the Fourteenth Amendment." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 52 (1999). On this point, the Sixth Circuit has stated:

> This circuit recognizes three tests for determining whether private conduct is fairly attributable to the state: the public function test, the state compulsion test, and the nexus test. The public function test requires that the private entity exercise powers which are traditionally exclusively reserved to the state. . . . The state compulsion test requires proof that the state significantly encouraged or somehow coerced the private party, either overtly or covertly, to take a particular action so that the choice is really that of the state. Finally, the nexus test requires a sufficiently close relationship (i.e., through state regulation or contract) between the state and the private actor so that the action taken may be attributed to the state.

*Tahfs v. Proctor*, 316 F.3d 584, 591 (6th Cir. 2003). Furthermore, to establish Article III standing—which may be challenged at any time—"there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (cleaned up).

While MDHHS does provide extensive training, education, and resources to healthcare providers, this is done for the purpose of ensuring parents provide informed consent allowing retained, deidentified DBS to be used for research purposes. To the extent the State is exercising any decision-making authority, it is directing health

professionals to seek and obtain informed consent. That failure to seek informed consent is a misdemeanor only highlights that such a failure is not authorized or encouraged by the State. If, at the time Plaintiff-Children were born, the healthcare professionals did not comply with these requirements, Plaintiffs are free to file complaints with MDHHS and, perhaps, their local prosecutors, but the State is not the right defendant to Plaintiffs' claims that their healthcare professionals failed to properly obtain informed consent. Thus, Defendants are entitled to summary judgment as a matter of law, and Plaintiffs' claims should be dismissed.

**E. There is no civil conspiracy.**

A civil conspiracy under § 1983 is "an agreement between two or more persons to injure another by unlawful action." *Revis v. Meldrum,* 489 F.3d 273, 290 (6th Cir. 2007). To prevail on such a claim, a plaintiff must show: (1) the existence of a single plan; (2) that the conspirators shared in a general conspiratorial objective to deprive the plaintiff of their constitutional rights; and (3) an overt act committed in furtherance of the conspiracy and that caused the alleged injury. *Hooks v. Hooks,* 771 F.2d 935, 944 (6th Cir. 1985).

Here, there is no question of material fact in the record whose answer could suggest that there was a plan, other than the mere existence of state law; that the State Defendants, and presumably Plaintiffs' healthcare providers, had a conspiratorial objective of violating Plaintiffs' constitutional rights; or that they agreed to conspire or otherwise acted in furtherance of a conspiracy that caused an injury. Thus, the State Defendants are entitled to judgment as a matter of law.

## II. Plaintiffs are not entitled to the extraordinary remedy of injunctive relief, and this Court should not grant the requested declaratory relief.

Plaintiffs cannot support a claim for injunctive relief. If there is an injury arising from the continued retention of DBS, that is only because Plaintiffs have failed to avail themselves of the opportunity to request destruction or return of the DBS. That failure continues to this day, defeating any suggestion that the injury is irreparable. And if the injury arose from the manner in which consent was sought, the injury cannot recur as Plaintiffs will not be asked again if they would like to make the Plaintiff-Children's DBS available for research, though they remain free to direct the use of those DBS.

Plaintiffs fail to meet the "well-established" four-factor test for injunctive relief: (1) that they have suffered an irreparable injury; (2) that remedies available at law are inadequate; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *Barry v. Lyon*, 834 F.3d 706, 720–21 (6th Cir. 2016) (citation omitted).

Plaintiffs cannot establish any of these factors. First, they have not suffered any injury, let alone an irreparable one. The DBS have not been used for any purpose contrary to the expressed wishes of Plaintiff-Parents. (Ex. 14; Ex. 15; Ex. 16; Ex. 17; Ex. 18; Ex. 19; Ex. 20; Ex. 21 at 6; Ex. 22 at 3.) In fact, Plaintiff-Children's DBS have not been used for any purpose following newborn screening. (Ex. 21 at 6; Ex. 22 at 3.) Second, Plaintiffs may submit a form at any time requesting destruction or return of the DBS at issue—an available remedy that is adequate. In fact, not only is this remedy adequate, it is essentially the relief sought by Plaintiffs. (*See* 1st Am. Compl. ¶¶ 118(f), (g), (h), ECF No. 26, PageID.331 (seeking destruction or return of Plaintiff-Children's DBS).) Third, the balance of hardships weighs in favor of having

Plaintiffs submit the simple form, rather than granting them overbroad relief that could adversely impact Michigan's successful newborn screening program. Fourth, given the tremendous value of the newborn screening program—saving the lives of newborns and identifying infants with diseases to form early treatment plans—which depends on retained DBS in order to continue effective operation, the public interest weighs in Defendants' favor. This Court should deny Plaintiffs' requested injunctive relief.

This Court should also decline to exercise its jurisdiction to grant Plaintiffs' requested declaratory relief. Declaratory relief is discretionary. *Grand Trunk W. R. Co. v. Consol. Rail Corp.*, 746 F.2d 323, 325 (6th Cir. 1984). The following five factors should guide this Court's discretion:

> (1) whether the declaratory action would settle the controversy; (2) whether the declaratory action would serve a useful purpose in clarifying the legal relations in issue; (3) whether the declaratory remedy is being used merely for the purpose of "procedural fencing" or "to provide an arena for a race for res judicata;" (4) whether the use of a declaratory action would increase friction between our federal and state courts and improperly encroach upon state jurisdiction; and (5) whether there is an alternative remedy which is better or more effective.

*Id.* at 326. These factors weigh against granting declaratory relief. Declaratory relief would not settle the matter. It would only create other controversies, primarily involving old policies and practices no longer in use by MDHHS or individuals not involved in this litigation. Nor would such relief clarify legal relations, because federal courts have recognized that the State can assert its interest in protecting children where necessary. *See, e.g.*, *Jacobson,* 197 U.S. at 38 (mandatory vaccinations); *Nikolao*, 875 F.3d at 316 (same); *Spiering*, 448 F. Supp. 2d 1129 (upholding mandatory newborn screening). A declaration here would also create friction because Michigan's Legislature has already stepped in to protect children through Mich. Comp. Laws § 333.5431. Further, it is apparent and has been acknowledged that this lawsuit is a precursor to future litigation, making it effectively procedural fencing. Finally, there is a more effective remedy: the parents can request the destruction or return of their children's DBS. This Court should decline to issue declaratory relief.

## CONCLUSION AND RELIEF REQUESTED

For the reasons stated above, the State Defendants respectfully request that this Honorable Court grant their motion under Rule 56 and grant summary judgment in favor of Defendants on all claims against them.

Respectfully submitted,

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Dated: April 5, 2021

**CERTIFICATE OF SERVICE (E-FILE)**

I hereby certify that on April 5, 2021, I electronically filed the above document(s) with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

*/s/Aaron W. Levin*
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U.S. DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI as parent-guardians and next friend to their minor children, D.W.L., R.F.K., and C.K.K.; SHANNON LAPORTE,

as parent-guardian and next friend to her minor children, M.T.L. and E.M.O.; and LYNNETTE WIEGAND, as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W., and M.L.W.,

Plaintiffs,

v

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES;ELIZABETH HERTEL, sued in her official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

Defendants.

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T. MORRIS

**INDEX OF EXHIBITS**

**Index of Exhibits:**

1. MDHHS Michigan Newborn Screening Questions and Answers
2. MDHHS Michigan Newborn Screening Pamphlet
3. MDHHS APF-111 – Newborn Screening Specimens
4. MDHHS Residual Newborn Screening Blood Spot Directive
5. Historical Directives to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses
6. Historical Directives to Destroy Newborn Screening Blood Specimen
7. MDHHS APF 114 – Guidelines for Research Use of Dried Blood Spots
8. MDHHS Application for Designation as a Medical Research Project & Approval Letter
9. MDHHS After Newborn Screening – Your Baby's Blood Spots
10. MDHHS BioTrust Frequently Asked Questions
11. MDHHS Michigan BioTrust for Health – Consent Options
12. BioTrust Research Consent Form
13. Institutional Review Board Approval Forms for Michigan Neonatal Biobank
14. Michigan BioTrust for Health blood spot directive dated April 22, 2013
15. Michigan BioTrust for Health blood spot directive dated February 10, 2016
16. Michigan BioTrust for Health blood spot directive dated February 6, 2017
17. Michigan BioTrust for Health blood spot directive dated November 22, 2011
18. Michigan BioTrust for Health blood spot directive dated July 18, 2013
19. Michigan BioTrust for Health blood spot directive dated December 25, 2014
20. Michigan BioTrust for Health blood spot directive dated January 30, 2017
21. Declaration of Mary Seeterlin
22. Declaration of Mary Kleyn

23. Deposition of Dr. Sarah Lyon-Callo
24. Deposition of Adam Kanuszewski
25. Deposition of Ashley Kanuszewski
26. Deposition of Shannon LaPorte
27. Deposition of Lynette Wiegand
28. Elizabeth R. Eisenhauer, *Mothers' Decisions About Donating Newborns' Blood Spots for Research*, 33 J. Perinat. Neonat. Nurs. 361 (2019)
29. Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 Minn. J.L. Sci. & Tech. 729 (2014)
30. Deposition of Dr. Antonio Yancey
31. Historical Newborn Screening Pamphlets
32. 45 C.F.R. § 46.116 effective June 23, 2005 to July 18, 2018
33. Deposition of Sonia Suter

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 1

## MDHHS Michigan Newborn Screening Questions and Answers

# Michigan Newborn Screening Questions and Answers

Newborn Screening is a public health program required by Michigan law to find babies with rare but serious disorders that require early treatment. All babies need to be tested in order to find the small number who look healthy but have a rare medical condition. Babies with these conditions seem healthy at birth but can become very sick in a short time. Each year more than 250 Michigan babies - one in every 400 to 500 births- are found to have a disorder detected by newborn screening.

Michigan Newborn Screening Main Page
Michigan Biotrust for Health Main Page



**Q. When did NBS begin?**
Newborn screening for a rare metabolic disease called phenylketonuria (PKU) began in 1965. PKU causes severe developmental delay and disability, but can be treated by limiting the amount of protein in the diet. Today, a child with PKU can have normal development when detected by NBS and treated early.

**Q. How many disorders can be found today?**
The number of disorders on the NBS panel has increased over the years as new technologies and treatments became available. The screening panel now includes 50+ disorders including hearing loss and critical congenital heart disease. If these disorders are not found and treated soon after birth, permanent disability, illness or death may result.

**Q. How many babies are found through bloodspot screening?**
Each year, more than 250 babies, or about 1 in 400 to 500 births, are found to have one of the disorders. Over the years, approximately 6,000 Michigan babies have been diagnosed and received treatment as a result of NBS.

**Q. What is Michigan's newborn screening law?**
Michigan's newborn screening law is part of the public health code. This law designates the state public health laboratory as a centralized site to perform NBS and establishes a fee for testing. It allows blood specimens to be used for medical research under certain conditions, and also lets parents ask the hospital to draw a second specimen to keep for themselves.

**Q. How much does newborn screening cost?**
The current cost is $125.83 for the first screen. This fee supports the laboratory costs of screening, follow-up, and medical management for infants and children affected by the disorders. Hospitals typically purchase a supply of newborn screening cards. The cost is included in the birthing and newborn nursery charges that are usually covered by insurance. The fee can be waived for families with financial hardship.

**Q. When is NBS done?**
Whether a baby is born in the hospital or at home, NBS should be done between 24 and 36 hours after birth.

**Q. How is NBS done?**
A few drops of blood are drawn from the heel. The blood sample is used to fill six circles on a filter paper card (shown below) and allowed to dry. It is then sent to the state public health laboratory at the Michigan Department of Health and Human Services (MDHHS) for testing. These samples are often called dried blood spots (DBS).

**Q. Why are six spots collected?**
Six spots are usually collected to be sure there are enough for all the tests. Sometimes not all the spots are suitable for testing, so it helps to have more than are needed. In the event there is a positive (abnormal) test, the lab can double check the result with the extra spots. Having six spots available limits the number of newborns who need to have their blood drawn again.

**Q. What happens if my baby has a positive (abnormal) screen?**
When there is a positive screen, parents will be contacted by their baby's physician. Sometimes only a repeat screening test is needed. In other instances, the baby will be referred to a medical management center for a diagnostic work-up and treatment if needed. Specialists will be available to work with the family, explaining the condition and next steps that should be taken to assure the best possible health outcome for a baby.

**Q. What happens to the NBS dried blood spot card after testing is complete?**
The laboratory saves one full blood spot circle for use by the child or family in case it is ever needed in the future. Because most babies have normal results and additional testing is not needed, a couple extra spots are often left over. All directly identifiable information (name, address, birth date, etc) is removed from these spots. They are labeled with a code, and then stored at the Michigan Neonatal Biobank, the storage facility for the Michigan BioTrust for Health.

**Q. What happens when a baby is born at home?**
Babies born at home should receive newborn screening. The midwife or birth attendant should collect the specimen and send it to the state laboratory. Parents planning a home birth can call 517-335-8887 ahead of time to purchase a newborn screening card.

**Q. How can parents learn about newborn screening?**
Every hospital receives newborn screening brochures that should be given to parents when a baby is born. Efforts are also underway to enhance outreach education about newborn screening for expectant parents, so they will be aware of newborn screening before delivery. More detailed information about newborn screening in Michigan can be found at www.michigan.gov/newbornscreening.

**These national websites also provide general information about newborn screening:**
March of Dimes NBS Overview
March of Dimes "A Parent's Guide to Newborn Screening" video
March of Dimes "A Parent's Guide to Newborn Screening" video en ESPAÑOL
National Library of Medicine NBS Resources
National Newborn Screening and Genetics Resource Center
Save Babies Through Screening Foundation
STAR-G (Screening, Technology and Research in Genetics)

**Q. What is the Michigan BioTrust for Health?**
The BioTrust is a public health initiative to make leftover newborn screening blood spot specimens more available for medical and health research. Learn more at www.michigan.gov/biotrust.

***Kanuszewski, et al v. MDHHS, et al.***
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# EXHIBIT 2

## MDHHS Michigan Newborn Screening Pamphlet

## Is there anything else I need to do?

**ASK** Hospital staff or your midwife if newborn screening was done.

**BE SURE** The hospital or midwife and your baby's healthcare provider have the right phone number and address to reach you.

**CHECK** With your baby's healthcare provider or midwife about the NBS results.

**FOLLOW** Directions from your baby's healthcare provider if more tests or medical appointments are needed.

***Saving babies since 1965***

## Would you like to learn more?

**Please talk to your baby's healthcare provider or contact us by:**

**Telephone:**
1-866-673-9939 (toll-free)

**Fax:**
517-335-9419

**Email**
newbornscreening@michigan.gov

MICHIGAN Newborn Screening

P.O. Box 30195
Lansing, MI 48909

**www.michigan.gov/newbornscreening**

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR



9/17

# Michigan Newborn Screening

***Saving babies since 1965***

Learn about blood spot screening…

## What is Newborn Screening (NBS)?

NBS is a program that screens all babies at 24-36 hours of age for rare but serious disorders. Michigan law requires newborn screening to make sure that babies who need treatment are found early. As part of newborn screening, your baby is checked for hearing loss and signs of critical congenital heart disease. A few drops of blood are also taken from your baby's heel to fill spots on a filter paper card. The card is sent to the State Newborn Screening Laboratory where blood spots are tested for over 50 different disorders that benefit from early treatment. This pamphlet describes newborn blood spot screening.

## My baby seems really healthy. Is NBS still needed?

**YES!** Whether your baby is born in a hospital, non-hospital setting or at home, screening should be done. Most babies with these disorders seem healthy at birth but can become very sick in a short time. If not treated early, serious health problems, severe developmental delay and even death can occur. NBS is the best way to find nearly all babies with these disorders as early as possible.

## What happens if screening suggests a health problem?

The NBS Follow-up Program will alert your baby's healthcare provider. You will get a call about what to do next, but it does not always mean your baby will have a problem. Additional testing may be needed.

## What are the disorders?

In Michigan, blood spot screening looks for over 50 disorders that may affect:

- Blood cells
- Brain development
- How the body breaks down nutrients from food
- Lungs and breathing
- Hormones
- How the body fights infection

Congenital hypothyroidism, sickle cell disease, and cystic fibrosis are some of the most common disorders. For a complete list, visit: www.michigan.gov/newbornscreening. NBS may also find some babies who are healthy carriers of these disorders.

## What happens if my baby has one of these disorders?

Help is available if your baby is found to have a disorder. Treatment usually begins early and continues through life. Each year, newborn blood spot screening finds about 270 Michigan babies with these medical disorders.

## How is the cost of NBS covered?

If your baby is born in a hospital, the cost is part of the hospital charge. If your baby is born in a non-hospital setting, the NBS card may be purchased online at www.michigan.gov/nbsorders or by calling 1-866-673-9939. Some homebirths may qualify for a free screening.

## What happens to my baby's blood spots after screening?

All of the blood spots are not always needed for screening. The lab saves one full blood spot for future use by you or your child, if it is ever needed. The remaining blood spots are sent for storage.

Remaining blood spots from newborn screening may be made available for future medical research with a parent's consent. To learn more, please read the Michigan BioTrust for Health pamphlet or visit www.michigan.gov/biotrust.

State law allows you to ask that a second blood spot sample be taken for your safekeeping. If you would like a second sample, please talk to your healthcare provider.

Forms are available if you want your child's blood spots destroyed after newborn screening is complete. Please call 1-866-673-9939 for more information or visit www.michigan.gov/newbornscreening.

***Kanuszewski, et al v. MDHHS, et al.***
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**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 3

## MDHHS APF 111 – Newborn Screening Specimens

## PURPOSE

The purpose of this policy is to establish for the Michigan Department of Health and Human Services (MDHHS) a retention schedule for newborn screening dried blood spot specimens.

## DEFINITIONS

**NBS**: Newborn screening is a comprehensive program that tests for and provides long and short term follow up and medical management for children with disorders identified through the program. (PA 368 of 1978, 333.5431, 333.5430).

**DBS**: Dried blood spot is the blood specimen collected from the heel of a newborn post- birth on a filter paper collection device. After drying, the blood and patient identifying information contained on the same paper collection device are sent to the MDHHS Bureau of Laboratories for testing.

## POLICY

MDHHS will maintain, or cause to be stored, newborn screening dried blood spots up to 100 years from specimen receipt date. A parent or legal guardian may request that their child's DBS not be used for any research by contacting MDHHS until their child reaches 18 years of age. Upon reaching 18 years of age, the individual must make the request. A parent or legal guardian may request that their child's specimen be destroyed by providing the name, date of birth and their relationship to the individual from whom the specimen was collected and must provide copies of the individual's birth certificate and a government-issued identification (for example, driver's license or passport) to confirm that they have authority to make such a request. Upon reaching 18 years of age, the individual must make the request and provide copies of their birth certificate and a government-issued identification.

MDHHS retains qualified ownership of DBS while in storage. The department may release part, or all, of the residual DBS upon written request of the individual for research studies or other uses. MDHHS may release part, or all, of the de-identified specimen for NBS quality assurance and test development or public health or medical research with appropriate approval of the departments scientific advisory panel and Institutional Review Board. MDHHS will reserve part of the specimen solely for the use of the individual or parent/guardian, unless requested otherwise by an authorized individual.

Retention schedules for DBS collected for other tests (such as HIV serology, lead) will be determined by Bureau of Laboratory policy.

## PROCEDURE

The Bureau of Laboratories Newborn Screening section manager:

- Processes and packages dried blood spots for storage and maintains specimen identification.
- Oversees and confirms in writing the destruction of specimens when request for destruction has been received and confirmed as authentic from the individual or parent or legal guardian of the individual.

The Bureau of Laboratory Administrator identifies resources for an adequate and secure storage environment of the dried blood spot specimens and assures this environment protects the integrity of the biological components of the specimen.

## REFERENCES

Association of Public Laboratories(APHL)/Programs/Newborn Screening & Genetics.

Therrell, B.L, H.W. Hannon, et al. 1996. Guidelines for the retention, storage and use of residual dried blood spot samples after newborn screening analysis: Statement of the Council of Regional Networks for Genetic Services. Biochemical and Molecular Med. 57:116-124. in US National Library Of Medicine National Institutes of Health.

MDHHS/Adult & Children's Services/Children & Families/Hereditary Disorders/ Michigan Newborn Screening Program/ State of Michigan Links: Michigan Bio Trust for Health:

- MDHHS-5680, Residual Newborn Screening Blood Spot Directive.

Michigan Public Health Code, Act 368 of 1978, 333.5431, 333.5430

## CONTACT

For additional information concerning this policy, contact the MDHHS Bureau of Laboratories.

***Kanuszewski, et al v. MDHHS, et al.***
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**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 4

## MDHHS Residual Newborn Screening Blood Spot Directive

# RESIDUAL NEWBORN SCREENING BLOOD SPOT DIRECTIVE

Michigan Department of Health and Human Services

| Child's Name at Birth | Date of Birth |
|---|---|
| Child's Current Name | Check Birth Order if Multiple Birth ☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th |
| Mother's Name at Time of Child's Birth | Hospital of Birth |

I am a legal representative* of the child named above. I am asking the Michigan Department of Health and Human Services (MDHHS) to (check one):

☐ Destroy **all** remaining blood spots. I understand that by checking this box, **NO** blood spots will be available for any future use including medical, identification, or research purposes.

☐ Destroy **only** the portion of blood spots stored for research use. I understand by checking this box, one blood spot will be held by MDHHS. I must direct any potential future use including medical, identification or research purposes.

☐ Store but **not** use blood spots for research after newborn screening is complete. I understand that the blood spots will be kept by the laboratory but not used for research of any kind unless directed in writing by me.

*** Legal representative** means a parent or guardian of a minor who has authority to act on behalf of the minor or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

| Signature of parent, guardian or other legal representative | | Relationship to Child | |
|---|---|---|---|
| Printed Name | | Date | |
| Street Address | City | Zip Code | Phone Number |

If you are asking MDHHS to destroy any blood spots, you must also attach a copy of **the birth certificate** belonging to the person whose blood spots are being destroyed **AND the driver's license, state issued identification card or passport** of the person who signed above.

**Return document(s) via:**

**Email:** biotrust@michigan.gov **Fax:** 517-335-9419 **or**
**Post Mail:** BioTrust Coordinator, NBS Follow-up Program, PO Box 30195, Lansing, MI 48909

| The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability. | **Authority:** Michigan Public Health Code, Act 368 of 1978 |
|---|---|

***Kanuszewski, et al v. MDHHS, et al.***
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**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 5

## Historical Directives to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses

*Michigan Department of Community Health*

# Directive to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses

*This form should be completed and signed by the legal representative* to request removal from any research uses of the remaining newborn screening blood specimen on the individual named below:*

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Order if Multiple Birth:<br>A B C D E |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am the legal representative of the child named above. By signing below, I hereby request the Michigan Department of Community Health, after newborn screening has been completed, to **not** use this child's blood specimen for possible future research. I understand that the specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

| | | | |
|---|---|---|---|
| Signature of mother, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |
| Signature of father, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means the parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

## ⇨Fax completed form to: (517) 335-9776

**OR**

## ⇨Mail to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

DCH-1465 Rev 6/2009

*Michigan Department of Community Health*

# Directive to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to **not** use my child's (or my own) blood specimen for possible future research after newborn screening is complete. I understand that the specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

| | | | |
|---|---|---|---|
| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

## ⇨Fax completed form to: (517) 335-9776

**OR**

## ⇨Mail to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

DCH-1465 Rev 2/2010

*Michigan Department of Community Health*

# Directive to Store But Not Use Dried Blood Spot Specimen For Research

*This form should be completed and signed by the legal representative* to request storage but no research use of the remaining newborn screening blood specimen on the individual named below:*

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Order if Multiple Birth:<br>A B C D E |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am the legal representative of the child named above. By signing below, I hereby request the Michigan Department of Community Health, after newborn screening has been completed, to **not** use this child's blood specimen for possible future research. I understand that the specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

| | | | |
|---|---|---|---|
| Signature of mother, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |
| Signature of father, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means the parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

**⇨Fax completed form to: (517) 335-9776**

**OR**

**⇨Mail to:**

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

DCH-1465 Rev 7/2012

*Michigan Department of Community Health*

# Directive to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Birth Order if Multiple Birth: 1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to **not** use my child's (or my own) blood specimen for possible future research after newborn screening is complete. I understand that the specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

| | | | |
|---|---|---|---|
| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

## ⇨Fax completed form to: (517) 335-9776

**OR**

## ⇨Mail to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

Please state why you are making this request. (*This will help improve the newborn screening program, but you do not have to complete this section*.)

☐ Privacy concerns ☐ Not comfortable with research ☐ Other:_____

_____

_____

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

DCH-1465 Rev 10/2014

*Michigan Department of Health and Human Services*

# Directive to Allow Storage of Residual Newborn Screening Blood Spot (DBS) Specimen BUT NOT Allow Research Use

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Health and Human Services to store but **not** use my child's (or my own) DBS specimen for research after newborn screening is complete. I understand that the DBS specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

| | | | |
|---|---|---|---|
| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

## ⇨Return completed form via:

**Email:** biotrust@michigan.gov ***or***
**Fax:** 517-335-9419 ***or***
**Postal Mail:** BioTrust Coordinator, NBS Follow-up Program, P.O. Box 30195, Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability. |

DCH-1465 Rev 4/2017

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 6

## Historical Directives to Destroy Newborn Screening Blood Specimen

*Michigan Department of Community Health*

# Directive to Destroy Residual Newborn Screening Blood Specimen

*This form should be completed and signed by the legal representative* to request destruction of remaining newborn screening blood specimen on the person named below:*

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Order if Multiple Birth:<br>A B C D E |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am the legal representative of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy my child's (or my own) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

| | | | |
|---|---|---|---|
| Signature of mother, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |
| Signature of father, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means the parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of:
**1) the child's birth certificate** and **2) driver's license, state-issued identification card, or passport** of person(s) who sign above. Additional identifying documents may be requested.

## ⇨Mail completed form with required copies to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

*Michigan Department of Community Health*

# Directive to Destroy Residual Newborn Screening Blood Specimen

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy my child's (or my own) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

| | | | |
|---|---|---|---|
| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of:
**1) the child's birth certificate** and **2) driver's license, state-issued identification card, or passport** of person(s) who signed above. Additional identifying documents may be requested.

## ⇨Mail completed form with required copies to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

*Michigan Department of Community Health*

# Directive to Destroy Residual Newborn Screening Blood Specimen

| | |
|---|---|
| Child's Name at Birth: | Date of Birth: |
| Child's Current Name: | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy my child's (or my own) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

| | | | |
|---|---|---|---|
| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of:
**1) the child's birth certificate** and **2) driver's license, state-issued identification card, or passport** of person(s) who signed above. Additional identifying documents may be requested.

## ⇨Mail completed form with required copies to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

Please state why you are making this request. (*This will help improve the newborn screening program, but you do not have to complete this section*.)

☐ Privacy concerns ☐ Not comfortable with research ☐ Other:_____

_____

_____

| | | |
|---|---|---|
| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |

DCH-1448 Rev 10/2014

*Michigan Department of Health and Human Services*

# Directive to Destroy Residual Newborn Screening Blood Spot (DBS) Specimen

| Child's Name at Birth: | Date of Birth: |
|---|---|
| Child's Current Name: | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth: |

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Health and Human Services to:

☐ Destroy all remaining DBS specimen. I understand that by destroying all of the DBS specimen, it will **NOT** be available for any future use including medical, identification, or research purposes.

***Or***

☐ Destroy only the portion of DBS specimen stored for research use. I understand by checking this box one blood spot from the DBS specimen will be held by MDHHS only for potential future use, including medical, identification or research purposes, directed by me (*legal representative).

| Signature of parent, guardian, or other legal representative: | | Relationship to child: | |
|---|---|---|---|
| Printed name: | | Date: | |
| Street Address: | City: | Zip: | Phone: |

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of:
**1) the child's birth certificate** and **2) driver's license, state-issued identification card, or passport** of person(s) who signed above. Additional identifying documents may be requested.

**⇨Return completed form with required copies via:**

**Email:** biotrust@michigan.gov ***or***
**Fax:** 517-335-9419 ***or***
**Postal Mail:** BioTrust Coordinator, NBS Follow-up Program, P.O. Box 30195, Lansing, MI 48909

| **Authority:** | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability. |
|---|---|---|

DCH-1448 Rev 10/2017

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 7

## MDHHS APF 114 - Guidelines for Research Use of Dried Blood Spots

## PURPOSE

The purpose of this policy is to provide the Michigan Department of Health and Human Services (MDHHS) guidelines for utilization of residual newborn screening dried blood spots (DBS) in health research.

## DEFINITIONS

**Community Values Advisory Board (CVAB)**: a board of representatives from the community at large as well as community based and state advocacy organizations established and appointed by the director or designee to advise the department on:

- Policies that govern the ways in which blood spots will be acquired and used for research.
- The governance structure of the BioTrust, including a meaningful role for the CVAB in ongoing BioTrust operations.
- Strategies and methods to assure ongoing community awareness and engagement for informing development, review and revision of BioTrust policies.

**Dried Blood Spot (DBS)**: the blood specimen collected from the heel of a newborn for screening for hereditary disorders, as required by the Michigan Public Health Code, Act 368 of 1978, MCL 333.5431.

**DBS Program Representative**: State Registrar, Director of Bureau of Laboratories, and Director of the Bureau of Epidemiology and Population Health or designee.

**Michigan Department of Health and Human Services (MDHHS) IRB**: MDHHS's Institutional Review Board established under MMDHHS's Federal Wide Assurance to review all human subjects' research that is sponsored by, or involves MDHHS.

**Institutional Review Board (IRB)** approval: approval of research by MDHHS's IRB.

**Material Transfer Agreement**: a contract governing the transfer of tangible research materials between two organizations and the recipient's intentions are for us in research purposes. The department has adopted definitions, terms, and conditions of the Uniform Biological Material Transfer Agreement (UBMTA) published in the Federal Register, vol. 60, March 8, 1995, page

12771 et seq. with the following exception. MDHHS has added additional terms and conditions that apply only to the transfer of newborn screening specimens for research.

**Michigan BioTrust for Health**: the initiative by the department to make residual DBS from newborn screening more useful for medical and public health research by storing these DBS in optimal conditions and promoting their availability to researchers.

**BioTrust Scientific Advisory Board**: a board of scientists established consistent with the requirements of Administrative Rule 325.9055 and appointed by the director, or designee, for participation on scientific advisory panels that review proposed research covered by this policy for scientific merit.

**BioTrust Scientific Review Panel**: a panel of at least three members selected from the BioTrust scientific advisory board to review a specific research proposal.

## POLICY

MDHHS allows use of DBS in health research after a research proposal is evaluated for scientific rigor; innovation and significance to medical and public health research; human subjects' protections; and ethical standards as outlined in the procedures below, based on guiding principles set forth below with input from the Community Values Advisory Board.

## PROCEDURE

### Promoting the Public's Health

Research priorities may include but are not limited to:

- Prenatal, childhood or adult-onset disorders.
- Environmental exposures.

Utilization of residual DBS is not approved for research pertaining to:

- Chemical, biological or nuclear warfare.
- Cosmetics.
- Other non-health related ventures unless for purposes related to injury or medical conditions.

Research priorities and restrictions will be re-assessed by the Michigan BioTrust Community Values Advisory Board (CVAB) annually and upon request by the department as technological and scientific advances occur.

**Establishing Review and Approval Process**

DBS specimens shall only be released to a researcher:

- Following review and approval by the BioTrust Scientific Advisory Board and the Michigan Department of Health and Human Services Institutional Review Board.
- Completion of a material transfer agreement.
- Completion of a DCH-1294, Data Use Agreement, (if applicable).

Members of a Review Panel, from the BioTrust Scientific Advisory Board, shall independently review each research protocol requesting utilization of DBS. Panel members are responsible for evaluating the study for scientific rigor, innovation and significance to medical and public health research, feasibility and consistency with the priorities and restrictions set forth above.

The Michigan Department of Health and Human Services Institutional Review Board, comprised of representatives from its various programs and members from the community, shall evaluate proposals to use DBS for research to assure compliance with US regulations that govern human subject's research (45 CFR 46) and adherence to the ethical principles of the Belmont Report.

In addition, the Michigan Department of Health and Human Services Institutional Review Board will rely on guidance from the department's Scientific Advisory Board evaluation of the scientific merit and the CVAB advice on acceptable areas of research, to evaluate the potential benefit of the research in relation to any risk.

Data housed by the department will only be linked to DBS and released if the data is de-identified or accompanied by written informed consent. Approval must be obtained from the responsible Michigan Department of Health and Human Services program or registry and a DCH-1294, Data Use Agreement, executed between MDHHS and the researcher.

## PROTECTING CONFIDENTIALITY

Specimens from the BioTrust and any related data cannot be released in an identifiable manner and may not be manipulated by the researcher to identify an individual, unless specific informed consent is obtained.

DBS will not be released for research using whole genome or whole exome sequencing technology unless specific informed consent is obtained.

Following completion of newborn screening, DBS specimens shall be de-identified, coded with a unique number and retained in a secure storage facility. MDHHS serves as the honest broker and maintains the sole link that would enable re-coding to identify a sample. The storage code does not contain nor is it derived from directly identifiable information, such as social security number, birth date, etc.

DBS specimens released to researchers shall be coded with a different unique number that does not contain any directly identifiable information. Any accompanying data shall only be released to a researcher after de-identification. Directly identifiable information, such as name or address, shall only be released to researchers when specific informed consent is obtained.

## PROVIDING INFORMATION TO THE PUBLIC

Scientists shall provide the department, while work is on-going, an abstract summarizing the aims of the research. Scientists shall provide the department, within one year of research completion (cessation of data analysis) or no later than the acceptance for publication, whichever comes first, a summary of the research results in aggregate form so that they can be made available to the public on a website and as required through procedures established under the Freedom of Information Act (FOIA). Upon request from the scientist, 1-year deadline may be extended by the department for good cause. MDHHS will be given citation(s) for all published work utilizing the DBS.

**RESERVING A DRIED BLOOD SPOT IN TRUST FOR THE PARENT OR CHILD**

The Michigan Department of Health and Human Services Bureau of Laboratories shall maintain a portion of every individual's DBS sample (for up to 100 years from specimen receipt date) for uses that could directly benefit the child or the child's parent or legal representative; and not allow that portion of the sample to be utilized for any research purposes through the BioTrust. Requests for such use shall be submitted in writing by the child's parent or legal representative, by the child upon reaching the age of 18 years, or by the adult child's legal representative.

**DESTROYING DRIED BLOOD SPOTS FOLLOWING PARENTAL/INDIVIDUAL (OVER 18 YEARS OF AGE) REQUEST**

A parent may request that their child's DBS sample be destroyed until their child reaches 18 years of age. Upon reaching 18 years of age, the individual over 18 years of age must make the request. Upon receipt of the directive to destroy form in the Michigan Department of Health and Human Services Bureau of Laboratories, the DBS sample will be destroyed by the laboratory manager in the presence of a witness. The requestor will receive a notification letter once the DBS sample has been destroyed.

**PRESERVING DRIED BLOOD SPOTS ASSOCIATED WITH NEWBORN SCREENING DIAGNOSES**

MDHHS and the Michigan Neonatal Biobank will take steps to preserve DBS associated with newborn screening diagnoses due to the rarity of their conditions and vast potential in future research. These DBS will not be used for random population based research and researchers will be told of this caveat. If an emergency were to occur at the storage facility, the Michigan Neonatal Biobank, these samples will also be given priority.

## SEEKING PUBLIC INPUT

The department shall establish mechanisms to seek input from the public and key stakeholders within the community on the research direction of the BioTrust that may modify the priorities set forth in this policy.

## REFERENCES

Administrative Policy Manual Legal (APL) 410, Freedom of Information Act.

APL 618, Institutional Review Board Policy and Procedure.

Administrative Policy Manual Facilities and Hospital (APF) 111, Newborn Screening Specimens.

DCH-1183(E) Authorization to Disclose Protected Health Information

DCH-1294 Data Use and Non-Disclosure Agreement

Human Subjects Research, 45 CFR 46

Michigan Administrative Code R 325.167, R 325.9055, R 325.9075

Michigan Public Health Code, Act 369 of 1978, MCL 333.2611, 333.2619, 333.5431, 333.5717, 333.5721, 333.9207, 333.9227

Uniform Biological Material Transfer Agreement (UBMTA), 60 CFR 12771

## CONTACT

For additional information concerning this policy, contact the Genomics and Genetic Disorders Section at 517-335-8887.

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 8

## MDHHS Application for Designation as a Medical Research Project & Approval Letter

6/2007

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

# Application
# Designation as a Medical Research Project

Under the provision of MCL333.2631-2635

Submit application to: Gregory Holzman, MD, MPH
Chief Medical Executive Michigan Department of Community Health
201 Townsend
Lansing, MI 48913

*Note: A separate application must be submitted for each research project.*

| OFFICE USE ONLY |
|---|
| Application # 0115 |
| Date Rec'd 6/23/09 |
| Reviewed By: GKH |
| APPROVED: YES X NO: |
| Date: 6/23/09 |

## I. NAME OR INDIVIDUAL MAKING REQUEST

| Project Director/Title | Phone # |
|---|---|
| Newborn Screening Stored Residual Dried Blood Spots<br>Frances Pouch Downes, Administrator | 335-8063 |

Organization (Include branch, division, department, etc.)

Bureau of Laboratories/ Public Health Administration

Street Address of P.O. Box – City, State, Zip Code

3350 N. Martin Luther King, Jr. Blvd
Lansing, MI 48909

## II. SUMMARY OF STUDY PROTOCOL OR PROJECT ACTIVITIES

Title of Project or Study

Newborn Screening Stored Residual Dried Blood Spots

Name & Address of sponsor(s) for this project (if any)

NA

Specify all sources of funding for this project

Currently storage fees are paid by the Newborn Screening restricted funds. Researchers requesting access to the spots are charged a fee. As the infrastructure of the Michigan BioTrust for Health develops and user fees increase, the cost of storage will be supported solely by user fees, grants and gifts.

Protection of Human Subject

Has this project been reviewed by an institutional review board for the protection of human subjects?
YES _x_ NO ___ If NO, indicate reason.

Informed Consent

Is there a written informed consent for use in this study?
YES ___ If YES, attach a copy of the consent form to this application. NO x

Comments: The DCH IRB approved exemption from informed consent for those DBS submitted for testing at DCH prior to Sept. 24, 2008. A process to obtain informed consent to store DBS is in development but will require information systems modifications, training hospital and birthing center personnel and development of information tools for expectant parents. This request however is to designate all stored DBS as a medical research project.

Provide brief justification as to why designation as a Medical Research Project is needed:

Upon completion of newborn screening testing, residual dried blood spot specimens are stored indefinitely according to DCH policy. The primary uses for the residual DBS include quality improvement/test development of investigational NBS disorders, parent- or guardian-directed medical research, crime victim identification and de-identified medical research. In order to protect the genetic and personal privacy of families and individuals with residual newborn screening dried blood spots, the program needs to limit access to these uses. As the existence of the DBS collection and the potential uses grow, we anticipate requests that are contrary to the intent of storage. Focus group input, confirm that particularly minority populations do not want the DBS to be used for such purposes as development of crime agency DNA libraries or insurance eligibility and rate setting. Also, the dried blood spots have been and will likely increasingly be linked to other public health registries and data bases. The medical research designation will assure that the data linkages are available to responsible researchers with protection of the privacy of the individuals. Each request for DBS or DBS-data linkages will be reviewed by the DCH IRB for ethical treatment of participants and the scientific rigor will be tested by the recommendations of the Michigan BioTrust for Health Scientific Review Board.

The following information should be included in the description of your study:

1. Primary focus: State the specific health or medical problems addressed or other conditions or concerns of this study.
2. Objectives: State the hypotheses to be tested, if any.
3. Analyses to be performed.
4. Linkage, if any, with other data files. Specify the source(s) of these files.
5. Release of Results: Detail how the results will be released, including interim and final reports and publications.

Upon completion, send copies to the Michigan Department of Community Health at the address listed at the top of this application.

## III. CONFIDENTIALITY OF IDENTIFIABLE DATA

A. **How is the confidentiality of identifiable data obtained as part of this research project to be maintained?**

*Identifiable data* refers to any information which would permit, directly or indirectly, the identification of any individual or establishment. Include an explanation of how such data will be stored, as well as how and when you plan to dispose of the data after your study is completed.

Only deidentified data and DBS will be released to researchers unless the individual or parent/guardian have instructed the department to release the DBS and designated to whom the DBS are to be released.

**Will your study require further investigation to obtain additional information from the individuals, next-of-kin, physicians, and/or other individuals or institutions?**

YES ____ If YES, answer questions 1 and 2 below. NO x

**1. Briefly describe the following:**

**A. Types of respondents to be contacted.**

**B. Information to be obtained from respondents.**

**C. Methods to be used in conducting such investigations.**

**D. Other organizations, co-investigators or consultants, if any, conducting the investigations.**

The Michigan Neonatal Biobank is storing a part of the archive but will eventually store a portion of each specimen. The Department will store the remaining part of each specimen.

**2. How will you maintain the confidentiality of identifiable data obtained from the follow back investigations?**

Include an explanation of how such data will be stored, as well as how and when you plan to dispose of the data after your study is completed.

DBS are stored at Michigan Neonatal BioBank with a barcode only. The BioBank does not have access to the Department information system that identifies the individual from whom the specimen was collected. Additionally, the BioBank will assign another random identification number when it is sent to a researcher.

## IV. OTHER DATA AND USES

A. **For the purpose of this research project as described in the protocol, will any of the identifiable data obtained from this project be used by other organizations (e.g., other divisions, agencies, consultants, contractors and/or subcontractors)?**

YES NO X

If YES, indicate the name of the organization(s) and role(s) in this research project. If the name is unknown at this time, indicate the type of organization(s). Describe the safeguards that exist (or will be implemented) to ensure that the data will be used solely for the purposes of this research project.

The stored residual DBS are used only within the Department for purposes of Bureau of Laboratories quality improvement. Data from the NBS laboratory information system are used by Hearing, MCIR, Vital Records. All requests are reviewed by the BOL Bureau Administrator.

B. **Will any of the identifiable data obtained for this project be used as a basis for legal, administrative, or other actions which may affect particular individuals or establishments as a result of their specific identification in this project?**

YES ____ If YES, indicate how the data will be used. NO X

C. **Will the identifiable data be used either directly or indirectly for any research project other than the other actions which may affect particular individuals or establishments as a result of their specific identification in this project?**

YES ____ If YES, briefly describe other research project(s) or purpose(s) for which the data will be used. NO X

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

'NNIFER M. GRANHOLM
GOVERNOR

JANET OLSZEWSKI
DIRECTOR

June 23, 2009

Frances Pouch Downes, DrPH
State Public Health Laboratory Director
Bureau of Laboratories
Michigan Department of Community Health
3350 N. MLK Blvd.
Lansing, Michigan 48909

Dear Dr. Downes:

This letter is to advise that the following medical research application has been reviewed and designated:

**APPROVED**

**Application #0715**

***Newborn Screening Stored Residual Dried Blood Spots***

Michigan's Public Health Code provides for this designation, under MCLS 333.2631 and 333.2632, assuring that information collected during the study from participating parties be kept confidential and used only for research purposes.

Sincerely,

Greg Holzman MD, MPH

Greg Holzman, MD, MPH
Chief Medical Executive

Enclosure – Application

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 9

## MDHHS After Newborn Screening - Your Baby's Blood Spots

## What are the risks if your baby's blood spots are used for research?

The risk is that your baby could be identified. The chance this will happen is very low. Many steps are taken to protect privacy.

## What steps are taken to protect privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. They are stored coded only with a number and not your child's name or identifying information. Details that could identify a child or family are removed. MDHHS has taken steps to keep blood spots secure. The highest level of protection, a "Certificate of Confidentiality" from the United States Department of Health and Human Services has been granted. Details are below:

### Certificate of Confidentiality

*US Department of Health and Human Services*
http://grants.nih.gov/grants/policy/coc/

- The BioTrust can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The BioTrust will use the Certificate to resist any demands for information that would identify you, except as explained below.
- The Certificate cannot be used to resist a demand for information from personnel of the U.S. federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
- It does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the BioTrust will not use the Certificate to withhold that information.

## Will you or your child benefit from blood spot research?

Blood spot research may not directly help you, your child or your family. You will not be paid if your child's blood spots are used. Your family will not get money if products (such as new drugs) ever come from the research. This type of research aims to improve the health of communities. You will help ensure all groups of people in our state are represented in research. You, or a family member, may also be helped by research looking at new ways to diagnose, prevent or treat disease.

## What are your choices for blood spot research?

You can say "yes" or "no" to blood spot research. You will be asked to check a box and sign a form found in your baby's newborn screening card. If you say "yes", all blood spots taken for newborn screening may be used, except for the blood spot saved for your own use if needed. If you say "no", blood spots will be stored but not used for research. You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

## Can you change your mind?

Yes. You can call MDHHS at any time if you change your mind about blood spot research. After turning 18, your child must make this request.

## What do you need to do?

**ASK** if you have questions.

**VISIT** www.michigan.gov/biotrust to read more about consent options.

**CALL** MDHHS if you still have questions about blood spots.

**MARK** your choice for blood spot research use on the BioTrust consent form and sign it.

**GET** your pink copy of the BioTrust consent form to take home.

### MDHHS Newborn Screening Program

Telephone:
(Toll Free) 1-866-673-9939

Email:
newbornscreening@michigan.gov

Website:
www.michigan.gov/newbornscreening

*For questions about your research rights or whom to contact in case of a research-related injury: please call the MDHHS IRB at 517-241-1928*

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

MDHHS is an equal opportunity employer, services and program provider.

10/17

# After Newborn Screening

# Your Baby's Blood Spots

Michigan BioTrust for Health
research for the future

*Learn More About the Facts and Choices You Need to Understand*

## *Dear Parents:*

Soon after birth a few drops of blood are taken from your baby's heel. These "blood spots" are used for newborn screening. This program is required by state law and screens all babies for rare disorders to ensure early treatment. Please read *"Michigan Newborn Screening"* for more facts. Hospital staff or your midwife has a copy for you or visit www.michigan.gov/newbornscreening.

## *What happens to blood spots after newborn screening?*

Often parts or whole blood spots end up not being used. Once newborn screening is done, the unused blood spots are stored for up to 100 years. These stored blood spots may be used by the state lab to perform quality control tests and improve newborn screening. Blood spots may also be used to add more tests to newborn screening.

One blood spot is also kept by the state lab for your personal use, if needed. Parents have used this blood spot to help diagnose a disease in their child or to find reasons for a child's untimely death.

The rest of the blood spots are stored at a secure site, the Michigan Neonatal Biobank (www.mnbb.org). These stored blood spots may be used for research approved by the Michigan Department of Health and Human Services (MDHHS). The choice to allow this research is ***yours*** to make.

## *What is the Michigan BioTrust for Health?*

The BioTrust is an MDHHS program created to oversee the research use of stored blood spots. One purpose of the BioTrust is to allow all groups of Michiganders to be part of research. Different groups help advise MDHHS on rules for research use of blood spots and suggest ways to inform the public. They include a Community Values Advisory Board with members from different organizations and the general public.

## *What type of research is done?*

Blood spots can only be used for studies to better understand diseases or improve the public's health. We cannot predict every type of study that will be done. Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins. Studies have already:

- Looked for causes of cancer, birth defects and other health concerns, like obesity
- Improved newborn screening methods
- Tested mercury levels to find out if pregnant mothers are eating safe amounts of fish

***For research guidelines and a list of studies visit***
www.michigan.gov/biotrust

## *What are the steps for using blood spots in research?*

**1. MDHHS approves the study:**

- BioTrust guidelines are met.
- Scientific Advisory Board(s) ensures the study is good science.
- Institutional Review Board(s) ensures subjects' rights are protected.

**2. MDHHS selects blood spots:**

- Blood spots are picked randomly, *or*
- Blood spots are picked because a researcher wants to study a specific group (such as people with cancer).

**3. Researcher gets blood spots:**

- Researchers are not told whose blood spot is provided.
- Data may be provided such as a diagnosis or year of birth.
- Information that can identify a person is not provided, unless that person is asked and consents.

**4. Researcher performs study:**

- Blood spots are studied.
- Results are recorded.
- Any left-over spots are destroyed.
- Study results are reported.

## *How many blood spots are stored and can be used for research?*

Each year over 100,000 babies are born in Michigan. Almost all of these babies have newborn screening. All of these blood spots are stored in the Biobank.

Today, blood spots from over five million people are stored. If you or your child was born after July 1984, your blood spots are included. If collected before May 2010, these blood spots can be used for research unless you or your child (after age 18) contacts MDHHS. You may ask for your spots to be destroyed. You may also ask that your spots remain stored, but not used in research. Please call MDHHS for more details (Toll-free 1-866-673-9939).

Stored blood spots collected after April 2010 can only be used for research if a parent or legal representative returns a signed consent form allowing it.

## *Will you or your child get blood spot research results?*

No. Personal research results are not provided. Researchers are not given data that can identify you or your child. This means you cannot receive research results. A table listing all research using blood spots is posted at www.michigan.gov/biotrust. Research findings are posted here when studies are done.

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 10

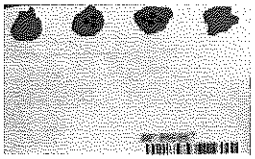
# MDHHS BioTrust Frequently Asked Questions

**BIOTRUST FREQUENTLY ASKED QUESTIONS**

# How Does the BioTrust Protect Your Privacy?

*There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. Blood spots are stored using a code and not a person's name. Details that could pinpoint a child or family are removed. The Department of Health and Human Services (MDHHS) has been granted the highest level of protection, a Certificate of Confidentiality from the United States Department of Health and Human Services.*

Blood spots are separated from the newborn screening card and labeled with a storage code, then sent to the Michigan Neonatal Biobank for storage.



Requests for blood spots and data must be approved by MDHHS Institutional Review Board, BioTrust Scientific Advisory Board and MDHHS Programs.

Michigan BioTrust for Health

Michigan Neonatal Biobank replaces storage code with a research code. Blood spots labeled with the research code given to researcher.

MNB michigan neonatal biobank

**1** After newborn screening is completed, the filter paper containing left-over blood spots is separated from the newborn screening card that has the baby's directly identifiable information. A code is assigned to five remaining blood spots before transfer to the Michigan Neonatal Biobank for storage. The same code is applied to the sixth blood spot that remains in the State Lab for storage in case a parent or person (over 18 years) needs the spot. The Michigan Neonatal Biobank can not access and does not receive any directly identifiable information.

**2** Research requests are reviewed and approved by the MDHHS Institutional Review Board and Scientific Advisory Board to ensure protection of human subjects. Both boards must approve a study before blood spots are released. If a research study requires samples meeting certain criteria or asks for accompanying data, the MDHHS Program housing the data must approve its release. MDHHS will then conduct database linkages to select the right blood spots while still keeping blood spots and data confidential and coded.

**3** Once MDHHS identifies the blood spots and potential data required for an approved study, the Biobank receives a list of storage codes to retrieve blood spots for the study. Before the blood spots and potential coded data are released to a researcher the Biobank assigns another, different code. Thus, the code a researcher sees is two steps removed from the original newborn screening card number.

***Researchers requesting identified blood spots or data must get consent from subjects for use in the specific study.***

# BIOTRUST FREQUENTLY ASKED QUESTIONS

## What are Your Options?

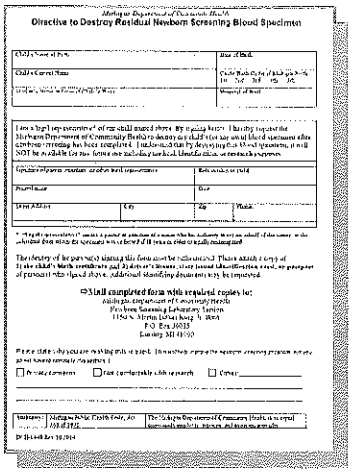
*For more details on your consent options please visit the "Consent" page on the BioTrust website. (www.michigan.gov/biotrust)*

**Were you or your child born in Michigan before July 1984?**

Blood spots received by the State Laboratory on infants born before July 1984 have been destroyed.

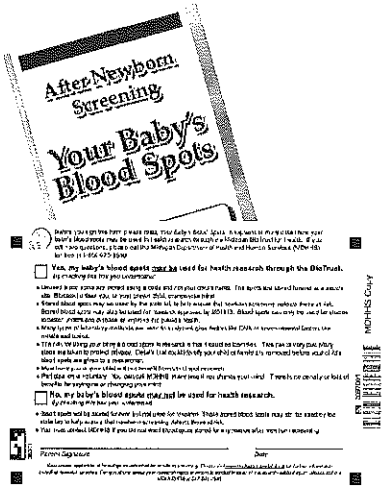
**Were you or your child born in Michigan between July 1984 and May 1, 2010?**

Today, blood spots from over four million people are stored. Blood spots collected between July 1984 and May 1, 2010, are coded and may be used in health research under a waiver of informed consent granted by the Michigan Department of Health and Human Services (MDHHS) Institutional Review Board. These blood spots may also be requested by a parent or person (>18y) for their own use. If you want to continue to allow the use of coded blood spots in health research, you do not need to do anything. If you do not want your or your child's blood spots made available for future health research you have two options to **opt-out**. You may fill out a form to: (1) request that blood spots remain stored but not used in future research, or (2) request that blood spots be destroyed. The lab requires verification that you are the legal representative entitled to make the request to destroy blood spots. You must submit your State ID or driver's license as well as a copy of your child's birth certificate.


Directive to Destroy Residual Newborn Screening Blood Specimen

**Was your child born in Michigan after April 30, 2010?**

Blood spots from an infant born after April 30, 2010, will be stored indefinitely (forever) after newborn screening is done. However, the blood spots will not be used in research through the BioTrust unless a signed parental consent form is on file with the State Laboratory. New parents are given a BioTrust consent form to record whether "yes" they want blood spots made available for research or "no" they do not. One full blood spot will still be saved for future use by the child or family, should it ever be needed. *Please note, if a parent declines participation in the BioTrust, blood spots are still stored unless a form to destroy the blood spots is returned to the State Laboratory.*




***To make a personal choice about blood spot use, please contact the Michigan Department of Health and Human Services.***

Call 1-866-673-9939 or Email *biotrust@michigan.gov*

*www.michigan.gov/biotrust*

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 11

# MDHHS Michigan BioTrust for Health - Consent Options

# Michigan BioTrust for Health - Consent Options

*Prior to making a decision about participation in the BioTrust, please make sure you read the Frequently Asked Questions section of this website and get all of your questions answered.*

The consent process differs depending on your or your child's date of birth. It is important to take a moment to learn more about the opt-out process for "legacy" blood spots, those collected prior to May 1, 2010. Please also read more about the opt-in process for "prospective" blood spots, those collected after April 30, 2010 through present day.

**Background**

Blood spots have always been stored for some period of time following newborn screening, but the length of time has changed over the years. In the 1970s, samples were saved for 7 years. In the 1980s, the Michigan Department of Health and Human Services (MDHHS) changed the policy to store each sample for 21.5 years following the receipt of legal advice. In 2008, the policy was revised for indefinite storage of blood spots to align with a recommendation from the Governor's Commission on Genetic Privacy and Progress. Today, blood spots are stored for up to 100 years once newborn screening is completed. The changes in storage policy have allowed for a collection of stored blood spots dating back to July 1984. **Any samples received by the state laboratory on infants born before July 1984 have been destroyed.**

**Opt-Out Process for Births Between July 1984 and April 30, 2010**

Blood spots collected between October 1987 and April 30, 2010 are stored for up to 100 years. Blood spots collected between July 1984 and September 1987 are scheduled to be destroyed per the MDHHS Bureau of Laboratories' retention schedule. These stored spots are de-identified and may be used in health research under a waiver of informed consent granted by the MDHHS Institutional Review Board. The stored blood spots may also be requested by a parent or person (>18y) for their own use. If you or your child were born between July 1984 and April 30, 2010, and you want to continue allowing the use of the de-identified blood spots in research, you do not need to do anything. If you do not want your or your child's stored blood spots used for future health research, there are two options to **opt-out**. You may fill out a form to: (1) request that the blood spots continue to be stored but not used for research, or (2) request that the blood spots be destroyed. If you ask for the blood spots to be destroyed, the laboratory requires verification that you are the legal representative entitled to make the request. Call 1-866-673-9939 or email newbornscreening@michigan.gov to obtain a form, or download:

- Residual Newborn Screening Blood Spot Directive
- DCH 1465 Directive to Store But Not Use Dried Blood Spot Specimen For Research (Arabic) (Spanish)
- Directive to Destroy Residual NBS Blood Specimen (Arabic) (Spanish)

**Opt-In Process for Births After April 30, 2010**

Blood spots from an infant born after April 30, 2010, will be stored for up to 100 years after newborn screening is done. However, the blood spots will not be used in research through the BioTrust unless a signed parental consent form is on file with the state laboratory. This new **opt-in** process began May 1, 2010. Currently, all birthing hospitals and midwives have been instructed to give new parents the option of signing a consent form after delivery if they want their child's remaining blood spots made available for future medical research. One full blood spot will also be saved for future use by the child or family, should

it ever be needed. After signing the consent form, parents can still change their mind later using the directive forms above.

****Please note, if a parent declines participation in the BioTrust blood spots are still stored for up to 100 years unless a Residual Newborn Screening Blood Spot Directive requesting destruction is returned to the state laboratory.****

- After Newborn Screening Your Baby's Blood Spots - Michigan BioTrust For Health Consent Brochure English
- After Newborn Screening Your Baby's Blood Spots - Michigan BioTrust for Health Consent Brochure Spanish Arabic
- Audio Recording of BioTrust Consent Brochure
- BioTrust Consent Form English
- BioTrust Alternate Consent Form
- Directive to use DBS for research English

BioTrust Main Page
NBS Main Page

*Updated 1-25-2018*

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 12

## BioTrust Research Consent Form

Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

☐ **Yes, my baby's blood spots <u>may be</u> used for health research through the BioTrust.**
*By checking this box you understand:*

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

☐ **No, my baby's blood spots <u>may not</u> be used for health research.**
*By checking this box you understand:*

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

MDHHS Copy

SN 2097001

38371

*Parent Signature* _____ *Date* _____

*Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.*

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 13

## Institutional Review Board Approval Forms for Michigan Neonatal Biobank

# Michigan Department of Community Health
# Institutional Review Board Approval Form

Authority: Code of Federal Regulations Title 45 part 46

| | | |
|---|---|---|
| **To:** | Kevin Cavanagh | "Responsible MDCH Employee" |
| **From:** | Harry McGee | MDCH IRB Chair/Administrator |
| **CC:** | Frances Pouch Downes | MDCH Bureau/Center/Office Director |

**MDCH IRB Log#:** 628-PHALAB **Date Received**: 11/18/08

**Study Title:** Michigan Neonatal BioBank (specimens collected prior to 9/24/2008)

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** NA

**Committee Action/Recommendation:**

- ☐ Decision Deferred *
- ☐ Exempt from review *
- ☐ Exempt from approval*
- ☐ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☒ Approved by full committee without modifications
- ☐ Approved by full committee with modifications*
- ☐ Disapproved*

**Comments**: * Waiver of informed consent granted based upon satisfying the criteria in 45 CFR 46.116(d). Please note we based satisfaction for criterion (4) on the understanding that some effort would be made to provide a general public notice that one can have their blood, or their child's blood, excluded from research use, e.g. a website posting, press release, etc. Please provide information on how that will be done when plans are finalized. The expiration date below would only apply if the current collection of bloods is not transferred before this date.

**Signature (Chair):** H. McGee **Approval Date:** 11/18/08

****Expiration Date for the Approval of the Project:** 11/18/09

****Prior to this expiration date the project must be re-approved in order for human subject's research to continue.**

**The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected change or problem in the research is reported immediately to the MDCH IRB Chair at 517-241-0806 or mcgeeh@michigan.gov.**

# Michigan Department of Community Health
# Institutional Review Board Approval Form

Authority: Code of Federal Regulations Title 45 part 46

| | | |
|---|---|---|
| **To:** | Kevin Cavanagh | "Responsible MDCH Employee" |
| **From:** | Harry McGee | MDCH IRB Chair/Administrator |
| **CC:** | Frances Pouch Downes | MDCH Bureau/Center/Office Director |

**MDCH IRB Log#:** 628-PHALAB (1) **Date Received:** 12/01/09

**Study Title:** Michigan Neonatal BioBank (specimens collected prior to 05/01/2010)

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** NA

**Committee Action/Recommendation:**

- ☐ Decision Deferred *
- ☐ Exempt from review *
- ☐ Exempt from approval*
- ☒ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee without modifications
- ☐ Approved by full committee with modifications*
- ☐ Disapproved*

**Comments**: * Waiver of informed consent granted for additional spots from 09/24/2008 to 05/01/2010 based upon satisfying the criteria in 45 CFR 46.116(d).

**Signature (Chair):** H. McGee **Approval Date:** 07/06/10

****Expiration Date for the Approval of the Project:** 12/01/10

****Prior to this expiration date the project must be re-approved in order for human subject's research to continue.**

**The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected change or problem in the research is reported immediately to the MDCH IRB Chair at 517-241-0806 or mcgeeh@michigan.gov.**

# Michigan Department of Community Health
# Institutional Review Board Approval Form

Authority: Code of Federal Regulations Title 45 part 46

| | | |
|---|---|---|
| **To:** | Kevin Cavanagh | "Responsible MDCH Employee" |
| **From:** | Harry McGee | MDCH IRB Chair/Administrator |
| **CC:** | Frances Pouch Downes | MDCH Bureau/Center/Office Director |

**MDCH IRB Log#:** 628-PHALAB (R) **Date Received**: 12/01/09

**Study Title:** Michigan Neonatal BioBank (specimens collected prior to 9/24/2008)

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** NA

**Committee Action/Recommendation:**

- ☐ Decision Deferred *
- ☐ Exempt from review *
- ☐ Exempt from approval*
- ☐ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☒ Approved by full committee without modifications
- ☐ Approved by full committee with modifications*
- ☐ Disapproved*

**Comments**: * Committee voted to bump this down to expedited review. There was a lapse in approval from 11/18/09 until 12/01/09. Waiver of informed consent previously granted based upon satisfying the criteria in 45 CFR 46.116(d). Please note we based satisfaction for criterion (4) on the understanding that some effort would be made to provide a general public notice that one can have their blood, or their child's blood, excluded from research use, e.g. a website posting, press release, etc. Please provide information on how that will be done when plans are finalized. The expiration date below would only apply if the current collection of bloods is not transferred before this date.

**Signature (Chair):** H. McGee **Approval Date:** 12/01/09

****Expiration Date for the Approval of the Project:** 12/01/10

****Prior to this expiration date the project must be re-approved in order for human subject's research to continue.**

**The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected change or problem in the research is reported immediately to the MDCH IRB Chair at 517-241-0806 or mcgeeh@michigan.gov.**

# Michigan Department of Community Health
# Institutional Review Board Approval Form

Authority: Code of Federal Regulations Title 45 part 46

| | | |
|---|---|---|
| **To:** | Kevin Cavanagh | "Responsible MDCH Employee" |
| **From:** | Harry McGee | MDCH IRB Chair/Administrator |
| **CC:** | Frances Pouch Downes | MDCH Bureau/Center/Office Director |

**MDCH IRB Log#:** 628-PHALAB (R) **Date Received:** 11/16/10

**Study Title:** Michigan Neonatal BioBank (specimens collected prior to 9/24/2008)

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** NA

**Committee Action/Recommendation:**

- ☐ Decision Deferred *
- ☐ Exempt from review *
- ☐ Exempt from approval*
- ☒ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee without modifications
- ☐ Approved by full committee with modifications*
- ☐ Disapproved*

**Comments: ***

**Signature (Chair):** H. McGee **Approval Date:** 11/17/10

****Expiration Date for the Approval of the Project:** 12/01/11

****Prior to this expiration date the project must be re-approved in order for human subject's research to continue.**

**The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected change or problem in the research is reported immediately to the MDCH IRB Chair at 517-241-0806 or mcgeeh@michigan.gov.**

# Michigan Department of Community Health
# Institutional Review Board Determination

Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297
Authority: Code of Federal Regulations Title 45 part 46

| | | |
|---|---|---|
| **To:** | Kevin Cavanagh | "Responsible MDCH Employee" |
| **From:** | Ian A. Horste | MDCH IRB Chair/Administrator |
| **CC:** | Frances Pouch Downes | MDCH Bureau/Office Director |

**MDCH IRB Log #:** 628-PHALAB(2) **Date Received:** 06/24/11

**Study Title:** **Michigan Neonatal BioBank (specimens collected prior to 05/01/2010)**

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** N/A

**Committee Action/Recommendation:**

- ☐ Tabled
- ☐ Not human subjects research*
- ☐ Exempt*
- ☒ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments**:

**Signature (Chair):** Ian A. Horste **Date Approved**: 06/24/11

**Expiration Date****: 12/01/11

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair, at (517) 241-0806 or MDCH-IRB@michigan.gov.

# Michigan Department of Community Health
# Institutional Review Board Determination

Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297
Authority: Code of Federal Regulations Title 45 part 46

**To: Kevin Cavanagh** "Responsible MDCH Employee"

**From:** Ian Horste MDCH IRB Chair/Administrator

**CC:** Frances Pouch Downes MDCH Bureau/Office Director

**MDCH IRB Log #:** 628-PHALAB **Date Received:** 11/18/11

**Study Title: Michigan Neonatal BioBank (specimens collected prior to 5/01/2010)**

**Investigator(s):** Kevin Cavanagh, Frances Downes

**Funding Source(s):** N/A

**Committee Action/Recommendation:**

- ☐ Tabled
- ☐ Not human subjects research*
- ☐ Exempt*
- ☒ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments**:

**Signature (Chair):**  **Date Approved:** 11/18/11

**Expiration Date****: 12/01/12

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair, at (517) 241-1928 or MDCH-IRB@michigan.gov.

**Michigan Department of Community Health**
**Institutional Review Board for the Protection of Human Research Subjects**
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
E-mail: MDCH-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# MDCH IRB DETERMINATION NOTICE

| | |
|---|---|
| **To: Kevin Cavanagh** | "Responsible MDCH Employee" |
| **From: Ian Horste** | MDCH IRB Chair/Administrator |
| **CC: Sandip Shah** | MDCH Bureau/Office Director |

**MDCH IRB Log #: 628-PHALAB** **Date Received: 11/21/2012**

**Study Title: Michigan Neonatal BioBank (specimens collected prior to 5/01/2010)**

**Investigator(s): Kevin Cavanagh**

**Funding Source(s):**

**Committee Action/Recommendation:**

- ☐ Tabled*
- ☐ Not human subjects research*
- ☐ Exempt*
- ☒ Approved by expedited review without modifications*
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications*
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments**: N/A

**Signature (Chair):** [signature] **Date Approved: 11/26/2012**

**Expiration Date**: 12/01/2013**

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair at (517) 241-1928 or MDCH-IRB@michigan.gov.

**Michigan Department of Community Health**
**Institutional Review Board for the Protection of Human Research Subjects**
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
E-mail: MDCH-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# MDCH IRB DETERMINATION NOTICE

**To: Bonita Taffe** "Responsible MDCH Employee"

**From: Ian Horste** MDCH IRB Chair/Administrator

**CC: Sandip Shah** MDCH Bureau/Office Director

**MDCH IRB Log #: 628-PHALAB** **Date Received: 11/15/2013**

**Study Title: Michigan Neonatal BioBank (specimens collected prior to 05/01/2010)**

**Investigator(s): Bonita Taffe, Carrie Langbo**

**Funding Source(s):**

**Committee Action/Recommendation:**

- ☐ Tabled*
- ☐ Not human subjects research*
- ☐ Exempt*
- ☒ Approved by expedited review without modifications*
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications*
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments**: Approval continued including a waiver of the requirement for informed consent under 46.116 (d). Efforts to provide subjects information regarding their participation are noted and must continue.

**Signature (Chair):** Ian A Horste **Date Approved: 11/26/2013**

**Expiration Date**: 12/01/2014**

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair at (517) 241-1928 or MDCH-IRB@michigan.gov.

**Michigan Department of Community Health**
**Institutional Review Board for the Protection of Human Research Subjects**
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
E-mail: MDCH-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# MDCH IRB DETERMINATION NOTICE

| | |
|---|---|
| **To: Janice Bach** | "Responsible MDCH Employee" |
| **From: Ian Horste** | MDCH IRB Chair/Administrator |
| **CC: Sarah Lyon-Callo** | MDCH Bureau/Office Director |

**MDCH IRB Log #: 628-PHA-EA** **Date Received: 11/24/2014**

**Study Title: The Michigan BioTrust for Health**

**Investigator(s): Carrie Langbo, Janice Bach**

**Funding Source(s):**

**Committee Action/Recommendation:**

- ☐ Tabled*
- ☐ Not human subjects research*
- ☐ Exempt*
- ☒ Approved by expedited review without modifications*
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications*
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments**: Ongoing approval continued for the storage and potential research use of specimens included in The Michigan BioTrust for Health. Provisions for informed consent continue to be required for specimens obtained prospectively. The waiver of requirements for informed consent is continued for those specimens obtained prior to 5/1/2010.

**Signature (Chair):** Ian Horste **Date Approved: 11/24/2014**

**Expiration Date**: 12/01/2015**

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair at (517) 241-1928 or MDCH-IRB@michigan.gov.

**Michigan Department of Health and Human Services**
**Institutional Review Board for the Protection of Human Research Subjects**
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

| | |
|---|---|
| **To: Janice Bach** | Responsible Department Employee |
| **From: Ian A. Horste** | Institutional Review Board Chair |
| **CC: Sarah Lyon-Callo** | Authorizing Bureau/Office Director |

**MDHHS IRB Log #: 628-PHA-FC-(R)** **Date Received: 11/13/2015**

**Study Title: The Michigan Bio Trust for Health**

**Primary Investigator(s): Janice Bach, Carrie Langbo**

**Funding Source(s): Non-Federal - Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments:** Approval continued for ongoing subject enrollment under the approved informed consent process. Also included is approval of the waiver of the requirement for informed consent for subjects whose specimens were obtained prior to May 1, 2010.

**Chair Signature:** Ian A Horste **Determination Date: 12/01/2015**

**Expiration Date*: 12/01/2016**

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

**Michigan Department of Health and Human Services**
**Institutional Review Board for the Protection of Human Research Subjects**
South Grand Building, 5th Floor, 333 S. Grand Ave., P.O. Box 30195, Lansing, MI 48909
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

| | | |
|---|---|---|
| **To:** | **Janice Bach** | Responsible Department Employee |
| **From:** | **Ian A. Horste** | Institutional Review Board Chair |
| **CC:** | **Patricia McKane** | Authorizing Bureau/Office Director |

**MDHHS IRB Log #: 628-PHA-FC** **Date Received: 10/13/2016**

**Study Title: The Michigan BioTrust for Health**

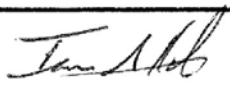
**Primary Investigator(s): Janice Bach, Carrie Langbo**

**Funding Source(s): Non-Federal, Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments:** Approval continued for ongoing new subject enrollment under the approved informed consent process. Also included in this renewed approval is approval of the waiver of the requirements for informed consent for subjects whose specimens were obtained prior to May 1, 2010.

**Chair Signature:**  **Determination Date: 11/01/2016**

**Expiration Date*: 12/01/2017**

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

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E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

**To:** **Janice Bach** Responsible Department Employee

**From:** **Ian A. Horste** Institutional Review Board Chair

**CC:** **Sarah Lyon-Callo** Authorizing Bureau/Office Director

**MDHHS IRB Log #: 628-PHA-FC** **Date Received: 10/18/2017**

**Study Title: The Michigan BioTrust for Health**

**Primary Investigator(s): Janice Bach; Carrie Langbo**

**Funding Source(s): Non-Federal - Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments:** MDHHS IRB full committee approval is continued, but includes a requirement for quarterly reporting to the IRB of error rates in appropriately recording consent decisions in LifeCycle along with discussion on methods being implemented to prevent the release of a specimen for research use when informed consent for such use has not been obtained. For example, the BioTrust could manually verify informed consent for each specimen to be released for research use at the time the specimen is selected for that research. Included in this determination is ongoing approval of the previously approved waiver of the requirements for informed consent as it pertains to archived specimens collected prior to implementation of the prospective informed consent process.

**Chair Signature:**  **Determination Date: 11/07/2017**

**Expiration Date*: 12/01/2018**

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

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E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

| | | |
|---|---|---|
| **To:** | **Shelby Atkinson** | Responsible Department Employee |
| **From:** | **Ian A. Horste** | Institutional Review Board Chair |
| **CC:** | **Sarah Lyon-Callo** | Authorizing Bureau/Office Director |

**MDHHS IRB Log #: 628-PHA-FC** **Date Received: 10/12/2018**

**Study Title: The Michigan BioTrust for Health**

**Primary Investigator(s): Patricia McKane**

**Funding Source(s): Non-Federal - Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments**: Included in this determination is MDHHS IRB approval for the change in Primary Investigator as well as the revised BioTrust Alternate Parental Consent Form: Newborn Screening Blood Spot Research Use. Changes proposed do not affect risks to subjects.

**Chair Signature:** Ian A Horste **Determination Date: 11/13/2018**

**Expiration Date*: 12/01/2019**

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

**Michigan Department of Health and Human Services**
**Institutional Review Board for the Protection of Human Research Subjects**
South Grand Building, 5th Floor, 333 S. Grand Ave., P.O. Box 30195, Lansing, MI 48909
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

| | | |
|---|---|---|
| **To:** | **Shelby Atkinson** | Responsible Department Employee |
| **From:** | **Ian A. Horste** | Institutional Review Board Chair |
| **CC:** | **Sarah Lyon-Callo** | Authorizing Bureau/Office Director |

**MDHHS IRB Log #: 628-PHA-FC** **Date Received: 10/16/2019**

**Study Title: The Michigan BioTrust for Health**

**Primary Investigator(s): Patricia McKane**

**Funding Source(s): Non-Federal - Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments**: This research remains eligible for approval under the pre-2018 Common Rule requirements. Previously established waivers of informed consent/parental permission requirements (i.e., the complete waiver for those subjects whose specimens were obtained before implementation of the BioTrust informed consent process, and the partial waiver for those subjects whose parental consent was obtained on a consent document required for use in combination with the BioTrust informational pamphlet) remain in effect. The ability to opt-out of BioTrust participation remains a requirement for the approved waivers of informed consent requirements.

**Chair Signature:** Ian A Horste **Determination Date: 11/05/2019**

**Expiration Date*: 12/01/2020**

**Human subjects research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

For expedited review and full committee review studies, the MDHHS IRB must approve any change to the study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unanticipated problem or severe adverse event in approved human subjects research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

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E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

# DETERMINATION NOTICE

**To:** **Shelby Atkinson** Responsible Department Employee

**From:** **Ian A. Horste** Institutional Review Board Chair

**CC:** **Sarah Lyon-Callo** Authorizing Bureau/Office Director

**MDHHS IRB Log #: 628-PHA-FC** **Date Received: 10/20/2020**

**Study Title: The Michigan BioTrust for Health**

**Primary Investigator(s): Patricia McKane**

**Funding Source(s): Non-Federal - Unspecified**

**Committee Action/Determination Type:**

- ☐ Tabled
- ☐ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☒ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

**Comments**: This research remains eligible for continued approval under the pre-2018 Common Rule requirements. Established waivers of informed consent/parental permission requirements remain in effect as previously documented for the subject population to which those waivers apply. The ability of those subjects (or the parents of those subjects) to opt-out of participation in research remains a requirement for the approved waivers. The provisions for obtaining parental consent to prospective participation in the Michigan BioTrust for Health remains appropriate for the involvement of children's neonatal dried blood spots in BioTrust approved research.

**Chair Signature:**  **Determination Date: 11/10/2020**

**Expiration Date*: 12/01/2021**
**Human subjects research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

For expedited review and full committee review studies, the MDHHS IRB must approve any change to the study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unanticipated problem or severe adverse event in approved human subjects research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 14

## Michigan BioTrust for Health Blood Spot Directive Dated April 22, 2013

Michigan BioTrust for Health
research for the future

Baby Name

Affix Label Here if Desired

**Admin. Use Only**

☒ Information Provided to Parent

☐ Parent Declined

You should have been given the booklet, *"After Newborn Screening"*. If not, please ask for it. This booklet describes the **Michigan BioTrust for Health** and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program at *1-866-673-9939*.

- Participation in the Michigan BioTrust for Health is completely voluntary.
- If I say "yes" now I may change my mind at any time and ask that my child's DBS not be used for research by calling *1-866-673-9939*.
- When my child is 18 he or she can ask that their DBS not be used for research.
- There is no penalty from not allowing my child's DBS to be used for research.

I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening.

38371

x Ashley Kamuszuski — 4-22-13

Parent Signature — Date

MI Dept of Community Health Laboratory Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 15

## Michigan BioTrust for Health Blood Spot Directive Dated February 10, 2016

Michigan BioTrust for Health
research for the future

Baby Name

Affix Label Here if Desired
Mark Parent Decision, Collect Signature, Return to MDCH

***Admin. Use Only***

Blood spots are stored indefinitely (forever). Blood spots labeled with a code can be used for health research through the BioTrust. The brochure, *Your Baby's Blood Spots*, gives details to help you make a choice about allowing your baby's blood spots to be used in health research. Please read this brochure. If you still have questions, please call the Department of Community Health *toll free* at: 1-866-673-9939.

| | |
|---|---|
| [X] Yes, my baby's blood spots may be used for health research. | [ ] No, my baby's blood spots may not be used for health research. |
| *This applies to all blood spots collected for newborn screening.* | *There is no penalty for saying no.* |

38371

Ashley Kanuszewski
Parent Signature

2-10-16
Date

MI Dept of Community Health Laboratory Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 16

## Michigan BioTrust for Health Blood Spot Directive Dated February 6, 2017

Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

☐ **Yes, my baby's blood spots may be used for health research through the BioTrust.**
*By checking this box you understand:*

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

☒ **No, my baby's blood spots may not be used for health research.**
*By checking this box you understand:*

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

[redacted]

*Parent Signature*

2/16/17
*Date*

38371

*Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.*

MDHHS Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 17

## Michigan BioTrust for Health Blood Spot Directive Dated November 22, 2011

Michigan BioTrust for Health

Baby Name

**Admin. Use Only**

☐ Information Provided to Parent

☐ Parent Declined

You should have been given the booklet, *"After Newborn Screening"*. If not, please ask for it. This booklet describes the **Michigan BioTrust for Health** and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program at *1-866-673-9939*.

- Participation in the Michigan BioTrust for Health is completely voluntary.
- If I say "yes" now I may change my mind at any time and ask that my child's DBS not be used for research by calling *1-866-673-9939*.
- When my child is 18 he or she can ask that their DBS not be used for research.
- There is no penalty from not allowing my child's DBS to be used for research.

I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening.

38371

Parent Signature

11-22-11
Date

MI Dept of Community Health Laboratory Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 18

## Michigan BioTrust for Health Blood Spot Directive Dated July 18, 2013

Michigan BioTrust for Health
research for the future

Baby Name: Wiegand, [redacted] Lynnette [redacted]
DOB: 7/17/2013 [redacted]
[redacted]

*Admin. Use Only*
☒ Information Provided to Parent
☐ Parent Declined

You should have been given the booklet, *"After Newborn Screening"*. If not, please ask for it. This booklet describes the **Michigan BioTrust for Health** and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program at *1-866-673-9939*.

- Participation in the Michigan BioTrust for Health is completely voluntary.
- If I say "yes" now I may change my mind at any time and ask that my child's DBS not be used for research by calling *1-866-673-9939*.
- When my child is 18 he or she can ask that their DBS not be used for research.
- There is no penalty from not allowing my child's DBS to be used for research.

I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening.

[redacted]

38371

x Lynnette M Wiegand
Parent Signature

7-18-13
Date

MI Dept of Community Health Laboratory Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 19

## Michigan BioTrust for Health Blood Spot Directive Dated December 25, 2014

Michigan BioTrust for Health
research for the future

Baby Na Wiegand, [redacted] Lynnette
DOB: 12/24/2014 [redacted]
Mark [redacted] urn to MDCH

*Admin: Use Only*

Blood spots are stored indefinitely (forever). Blood spots labeled with a code can be used for health research through the BioTrust. The brochure, *Your Baby's Blood Spots*, gives details to help you make a choice about allowing your baby's blood spots to be used in health research. Please read this brochure. If you still have questions, please call the Department of Community Health *toll free* at: 1-866-673-9939.

| | |
|---|---|
| ☒ Yes, my baby's blood spots may be used for health research. | ☐ No, my baby's blood spots may not be used for health research. |
| *This applies to all blood spots collected for newborn screening.* | *There is no penalty for saying no.* |

38371

Lynnette Wiegand
Parent Signature

12-25-14
Date

MI Dept of Community Health Laboratory Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 20

## Michigan BioTrust for Health Blood Spot Directive Dated January 30, 2017

Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

☐ **Yes, my baby's blood spots <u>may be</u> used for health research through the BioTrust.**
*By checking this box you understand:*

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

☒ **No, my baby's blood spots <u>may not</u> be used for health research.**
*By checking this box you understand:*

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

38371

Parent Signature _____ Date 1-30-17

*Your choice applies to all blood spots collected for newborn screening. Please visit <u>www.michigan.gov/biotrust</u> for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.*

MDHHS Copy

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 21

## Declaration of Mary Seeterlin

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI as parent-guardians and next friend to their minor children, D.W.L., R.F.K., and C.K.K.; SHANNON LAPORTE, as parent-guardian and next friend to her minor children, M.T.L. and E.M.O.; and LYNNETTE WIEGAND, as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W., and M.L.W.,

Plaintiffs,

v

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; ELIZABETH HERTEL, sued in her official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

Defendants.

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T. MORRIS

# DECLARATION OF MARY SEETERLIN

I, Mary Seeterlin, hereby depose and state as follows:

1. I am the Section Manager of the Newborn Screening Section at the Michigan Department of Health and Human Services Laboratory (MDHHS Laboratory). I have personal knowledge of the facts set forth in this Declaration and am competent to testify regarding such facts if called upon to do so.

2. Newborn screening measures dried blood spots (DBS) for approximately 100 analytes. Following screening, the amounts of these analytes in the blood and demographic data are retained. No other genetic information is tested for or retained.

3. The MDHHS Newborn Screening Laboratory does not have the equipment necessary to do genome sequencing.

4. Residual dried blood spots (DBS) are used for many Quality Improvement and Quality Assurance purposes by the Newborn Screening Laboratory. The newborn screening program could not operate without retaining DBS.

5. The Michigan Newborn Screening Laboratory, as part to the Michigan Bureau of Laboratories, is certified by the Clinical Laboratory Improvements Amendments (CLIA), which includes review by the Food and Drug Administration (FDA), Center for Medicare and Medicaid Services (CMS), and Centers for Disease Control and

Prevention (CDC). The Michigan Newborn Screening Laboratory is also College of American Pathologists (CAP) accredited. These accreditation agencies provide industry standards for the testing of human samples for diagnostic purposes. Having these certifications demonstrates that our Laboratory meets the federal regulations for clinical diagnostic testing, ensuring quality and safety in the laboratory and laboratory results.

6. CAP provides a core set of requirements for analytical validation/verification of method performance specifications that laboratories must perform for each test, method, or instrument system before use in patient testing. Many of these testing requirements involve the use of residual DBS.

7. For example, prior to clinical use of new instrumentation, the newborn screening laboratory must verify the method performance specifications. One of these specifications is the reportable range or reference interval. Typically, a minimum of 5,000 residual DBS specimens are needed to characterize the mean and standard deviation of our patient population, and more if the analyte varies with age of collection and birth weight.

8. Similar validation requirements include testing for Limit of Detection, Clinical Specificity, Clinical Sensitivity, verifying clinical determination, and establishing cutoffs claims. The newborn screening

laboratory has 9 different testing areas and over 29 instruments, resulting in transitions to new testing equipment virtually every year. The use of residual DBS specimens is essential for these vital laboratory improvements and ensuring the accuracy of equipment.

9. Disorders screened for by newborn screening are rare. In addition to analyzing thousands of normal DBS specimens, clinically confirmed positive DBS are vital for determining appropriate cutoffs. With some disorders having incidence rates as low as 1 affected infant in 350,000 screened, it is not possible to replace these rare samples and laboratory fabricated samples do not provide an adequate substitute.

10. Because newborn screening is not diagnostic testing, there are times when a child can have a disorder and have a screen that is within normal limits (false negative result). When the newborn screening laboratory is informed of a false negative result, all 6 spots of the residual DBS are retested for quality assurance purposes. Retesting is valuable for root cause analysis of the false negative event and allows for elucidation of causation between preanalytical, analytical, or post analytical origin.

11. The root cause analysis is vital if there is a determination there were no errors in method or processing of the DBS. This allows the Michigan newborn screening program to begin discussions with clinical partners and experts in the field about potential cutoff changes needed

to capture an infant as a positive screen and prevent future false negatives. False negative screens can have dire health outcomes for the infants and the Michigan newborn screening program takes these very seriously.

12. The retained data is crucial for our quality improvement studies, particularly cutoff evaluations. Right now, we are exploring changing the screening cutoffs for one of the disorders. This work was prompted by a false negative. We retrieved over 10 years of screening data, so we could review the effect of different proposed screening cutoffs on the number of positives and the number of false negatives. Having access to the data allows us to make evidence-based decisions and estimate the efforts of those decisions on families and clinical providers. Since most of the disorders are quite rare, it's important to combine data over many years in order to have statistical confidence. There are many examples of how NBS data has been used to improve the program.

13. When there are false negative results, archived data is needed for quality assurance review purposes. When a false negative is reported, the NBS program reviews the analyte value internally, and typically with the appropriate advisory committee, to determine if further exploration of cutoff changes is warranted.

14. Keeping the demographic data is critical for ensuring we are able to retrieve the correct blood spots for parent-directed requests, including sending DBS to a doctor's office to help with a diagnosis, parent-directed research, and return or destruction of the DBS. With missing data or name changes, we sometimes need to use multiple data fields to feel confident that we are identifying the correct blood spot.

15. Data is retained subject to the MDHHS Laboratory's retention policy. NBS blood spot cards, demographics, and Biotrust forms are retained for 35 years. NBS testing data is retained for 22 years.

16. I have reviewed MDHHS Laboratory records and confirmed that none of the nine plaintiff-children's dried blood spots were used for quality assurance, research, or any other purpose while stored at the MDHHS Laboratory after newborn screening testing was completed.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: 3/11/2021

Mary Seeterlin

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 22

## Declaration of Mary Kleyn

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI as parent-guardians and next friend to their minor children, D.W.L., R.F.K., and C.K.K.; SHANNON LAPORTE, as parent-guardian and next friend to her minor children, M.T.L. and E.M.O.; and LYNNETTE WIEGAND, as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W., and M.L.W.,

Plaintiffs,

v

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; ELIZABETH HERTEL, sued in her official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

Defendants.

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T. MORRIS

# DECLARATION OF MARY KLEYN

I, Mary Kleyn, hereby depose and state as follows:

1. I am the Manager of the Newborn Screening Follow-up Section at the Michigan Department of Health and Human Services (MDHHS). I have personal knowledge of the facts set forth in this Declaration and am competent to testify regarding such facts if called upon to do so.

2. Hospitals typically purchase a supply of newborn screening cards. The cost is included in the birthing and newborn nursery charges that are usually covered by insurance. The fee can be waived for families with financial hardship.

3. MDHHS destroys retained dried blood spots (DBS) upon receipt of a directive to destroy completed by an authorized individual, such as a parent, guardian, or an individual after reaching age 18.

4. In 2009, MDHHS destroyed DBS in response to 9 completed directives.
In 2010, DBS were destroyed in response to 32 completed directives.
In 2011, DBS were destroyed in response to 39 completed directives.
In 2012, DBS were destroyed in response to 48 completed directives.
In 2013, DBS were destroyed in response to 48 completed directives.
In 2014, DBS were destroyed in response to 43 completed directives.
In 2015, DBS were destroyed in response to 40 completed directives.
In 2016, DBS were destroyed in response to 24 completed directives.
In 2017, DBS were destroyed in response to 33 completed directives.

In 2018, DBS were destroyed in response to 45 completed directives.

In 2019, DBS were destroyed in response to 42 completed directives.

In 2020, DBS were destroyed in response to 34 completed directives.

As of March 3, 2021, in 2021 DBS were destroyed in response to 3 completed directives.

5. I have reviewed MDHHS departmental records and confirmed that no directive to destroy or request for return of DBS has been submitted on behalf of any Plaintiff.

6. I have reviewed MDHHS departmental records and confirmed that none of the nine plaintiff-children's DBS were used for research while stored at the Michigan Neonatal Biobank after newborn screening testing was completed.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: March 12, 2021

Mary Kleyn

Mary Kleyn

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 23

## Deposition of Dr. Sarah Lyon-Callo

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v Case No. 18-cv-10472

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, HON. THOMAS L. LUDINGTON
MAG. PATRICIA T. MORRIS

Defendants.

/

VIDEO CONFERENCE DEPOSITION OF SARAH LYON-CALLO, PH.D.

Taken by the Plaintiffs on the 17th day of December, 2020,

via Zoom, at 1:00 p.m.

APPEARANCES:

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Also Present:
Sandip Shah, Ph.D.
Eric Hendricks
Ashley Campbell

RECORDED BY: Pam Rankinen, CER 4532
Certified Electronic Recorder
Network Reporting Corporation
Firm Registration Number 8151
1-800-632-27201

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Via Zoom Video Conference

Thursday, December 17, 2020 - 1:01 p.m.

MR. ELLISON: Good afternoon. I guess I want to know -- I want to be respectful of how I addressed you. Is it just -- do I just call you "Doctor"? Would that be sufficient?

DR. LYON-CALLO: I'm fine if you all me Sarah, but that's really fine.

MR. ELLISON: Okay. All right. I mean no disrespect. As you can kind of tell, we're a little less than formal with the group that we've been hanging out together so long on this particular case. So, anyway, first of all, thank you for being here. I appreciate it. As you may have heard, I need to ask some questions of you here as part of the newborn screening lawsuit, which I'm sure you're aware of. Have you ever done a deposition before?

DR. LYON-CALLO: Yes, I have. I haven't done a deposition over Zoom before, but I've done depositions.

MR. ELLISON: Okay. All right. Well, then I'll skip the usual instructions then going forward, and we can just get right to the -- right to the heart of it here.

REPORTER: Do you solemnly swear or affirm that the testimony you’re about to give shall be the whole truth?

DR. LYON-CALLO: I do.

SARAH LYON-CALLO, PH.D.

having been called by the Plaintiffs and sworn:

EXAMINATION

BY MR. ELLISON:

Q I have a couple of questions regarding the newborn screening program and the Michigan Neonatal Biobank. And I just call it -- just for purposes of our discussion here today, when I refer to the "Biobank," I'm referring, of course, to the one that's headed by Dr. Yancey, the organization with its offices and operations in Detroit at the -- at Tech Town.

And then when I refer to the "newborn screening program," part of it, that's the state side, I would call it, of this particular setup. Is that agreeable that we can talk on those terms?

**A No. The newborn screening program is a screening program. The Michigan BioTrust is the state program that addresses the residual dried blood spots. The Michigan Neonatal Biobank is an entity that is managing the storage of those spots.**

Q Okay.

**A So I want to be -- I am very clear and precise in my language when I'm talking about the difference between newborn screening program versus the Michigan BioTrust for Health.**

Q Okay. So that's one of the questions I'm going to ask you

about. So I'm going to jump ahead and ask you that. I'm going to set it up in a particular way, and I want you to explain to me, thereafter, what happens. A newborn is born. Blood spots are extracted. Blood samples are extracted in the form of blood spots onto a Guthrie card and are sent to the Michigan State Laboratory for testing.

Once that testing is complete, I'd like you to explain to me, as best you know, what happens to those residual blood spots.

**A Sorry. I was having trouble with my mute. I think some of the particular detail regarding specifics around the mechanisms by which cards are handled directly after testing is best handled by Dr. Shah, the director of their laboratory. But I can share -- or I feel comfortable talking about the piece where -- that the dried blood spot card -- the newborn screen card, is -- there's a group at the laboratory that, when they are done with that card for the purposes of the newborn screening program, they process that card. The residual dried blood spots that become part of the --**

**(Dr. Shah enters deposition)**

Q Doctor -- excuse me. You said "they." Who is they?

**A The Bureau of Laboratories at the Michigan Department of Health and Human Services.**

Q Okay. Thank you.

**A Yup. You're welcome. And I see Dr. Shah has joined. I know this is my deposition, and he's like joining in. But he's joining in for his deposition time -- yeah, separate time; right?**

Q That's fine. He's entitled -- he's entitled to participate or to observe this -- the deposition as a party -- named party in the case. So, but go ahead.

**A Okay. Thank you.**

Q I apologize. I mean, I didn't mean to interrupt you. You used the pronoun, and I wanted to make sure I understood. You said, "Once 'they' were done processing the card."

**A Yes; yeah; yup. So when the laboratory staff are done with the card from a newborn screening perspective -- I'll let Dr. Shah get into the nitty-gritty of how that card is processed -- but the high level is that the residual dried blood spots go to -- with the exception of a spot reserved for parent/guardians, the residual dried blood spots go to the Michigan Neonatal Biobank where they are managed for the purposes of Michigan BioTrust.**

Q Okay. Who is responsible for overseeing the Michigan Neonatal Biobank as it applies to the Michigan -- from any individual you know at the Michigan Department of Health and Human Services?

**A I'm sorry. Can you repeat that one more time?**

Q Sure. What I want to understand is is that you just said

that the Michigan Neonatal Biobank stores -- and I'm paraphrasing -- stores newborn blood spots that are residual leftovers from the newborn testing program for -- on behalf of our -- under the control of the State of Michigan, I think, DHHS I think is what you said, or some variation thereof.

**A Uh-huh (affirmative).**

Q I'd like to know who at the Michigan Department of Health and Human Services is responsible for overseeing or otherwise controlling the blood spots at the Neonatal Biobank?

**A So the dried blood spots are managed by the Michigan BioTrust. That BioTrust structure has a community values advisory board, a scientific advisory board. There is also an internal infrastructure which Dr. Shah and myself are responsible for. But I think probably the simplest way to answer the question is that Dr. Shah and myself are responsible for the dried blood spots in the Michigan BioTrust program that are at the Michigan Neonatal Biobank for storage and distribution at the direction of the Michigan Department of Health and Human Services.**

Q Okay. Good. Fantastic. So I guess the reason why I'm asking would be is that if a -- say in this case a judge was to issue an injunction against both of you in your official capacities, you would have the ability to direct the blood

spots to no longer go to the Biobank if that's what the judge so ordered; would that be correct?

**A That is my understanding.**

Q Okay. And what -- as part of the complaint -- as part of my complaint and the research I did on this prior to bringing this complaint, I had you listed as the manager of the Michigan Bio- -- or excuse me -- Michigan BioTrust for Health; is that accurate?

**A So as the director of the Bureau of Epidemiology and Population Health, I am one of the two folks who is over the Michigan BioTrust for Health, the other one being Dr. Sandip Shah.**

Q Okay. What role does Mary Klein play in the Michigan Newborn Screening program and/or the Biobank?

**A So none of my -- so Mary Klein is a manager in the division of Lifecourse Epidemiology and Genomics, which is within the Bureau of Epidemiology and Population Health. So Mary Klein is in my supervisory chain. She does not -- I'm not quite certain how to answer part of your question. You asked about if she plays a role at the Michigan Neonatal Biobank? Is that what you asked me?**

Q Yeah. I want to understand, you mentioned that both you and Dr. Shah have supervisory control over the BioTrust. According to online disclosure forms that have been made available, that she is the manager of the newborn screening

section of the Michigan Department of Health and Human Services. I want to know what role, if any, does she play over the newborn screening program and/or the BioTrust. And I'll add to that -- or excuse me -- the Neonatal Biobank, and I'll add to that the BioTrust if that assists you.

**A So Mary Klein is the director of newborn screening section that addresses follow-up of results from the newborn screening program. In terms of Michigan BioTrust, she has a role in that as we get proposals for use of dried blood spots. She has a role also in communicating -- as do other staff as well -- in communicating with the Michigan Neonatal Biobank. She does not have a role within the Michigan Neonatal Biobank. So she's in no way an employee or something like that of the Michigan Neonatal Biobank.**

Q Okay. I've done the deposition of Dr. Antonio Yancey. Do you know who he is?

**A (No verbal response)**

Q I'm sorry. You've got to answer "yes" or "no."

**A Yes, I do. Yes, I do. Sorry. I'm trying -- I have a dog in the background.**

Q No problem. If I say "yes" -- yes, if I make a statement like that, I'm not trying to be rude. It's just sometimes we say things like "uh-huh's" and "um's," and we just have got to get clear for the record. So I mean no disrespect by it.

**A Yup.**

Q The -- one second here. I've got my email on, and it keeps beeping incessantly. There we go, stop that. Okay. I did the deposition of Dr. Yancey, and he indicated that the blood spots were not under the control of the board of directors but actually under the control of members -- or officials with the Michigan Department of Health and Human Services. Would you agree with that statement as I presented it to you?

**A Yes. The Michigan Neonatal Biobank does not have control over the use and distribution of the blood spots -- the residual dried blood spots.**

Q Okay. Who at the Michigan -- just to confirm -- who at the Michigan Department of Health and Human Services would be the person most in charge of decision-making as to the blood spots held at the Michigan Neonatal Biobank?

**A The use of the blood spots under the purposes of the Michigan BioTrust program, Dr. Sandip Shah and I are responsible for the decision-making around that and that includes the use -- or the instruction to the Michigan Neonatal Biobank.**

Q Okay. To your knowledge, is the Michigan Neonatal Biobank holding blood samples for any other purpose other than the Michigan BioTrust program?

**A I do not know the answer to that question.**

Q Well, do you have any knowledge -- do you have additional purposes or additional blood storage for any other programs, to your knowledge?

**A I don't have any knowledge to what else the Michigan Neonatal Biobank -- sorry -- what else the Michigan -- what else the entity at Tech Town -- the Biobank at Tech Town, what other activities they may have going.**

Q Okay. Can you explain -- and, again, acknowledging that we are lawyers and the person that's going to read this transcript hopefully ultimately will be a lawyer who is a judge. We're not scientists, by any means. Can you explain, as best you can, what the role of the Michigan BioTrust is, vis-a-vis, the Michigan Department of Health and Human Services?

**A So the Michigan BioTrust, it is a program that's run by the Michigan Department of Health and Human Services in order to oversee Michigan's storage residual dried blood spots and their use in health research.**

Q And I believe you just -- and just to confirm, you testified earlier that that program has oversight of the Michigan Neonatal Biobank; correct?

**A For the purposes of the residual dried blood spots, yes.**

Q Okay. Is there any other program or entities that have control over the Michigan Neonatal Biobank related to blood spots that you're aware of outside of the BioTrust?

**A You're referring to the residual dried blood spots from the Michigan Department of Health and Human Services? Is that what you're referring to?**

Q Any blood spots that you are aware of that are there. Is there any other entity or program that has any sort of role as it applies to the Biobank in any way, to your knowledge?

**A I think I shared with you earlier that I have no knowledge as to whether or not there are other forms of dried blood spots or other bio specimens that are at the Michigan Neonatal Biobank. The knowledge I have is related to the dried blood spots that are there from the Michigan BioTrust.**

Q Why are blood spots transferred or otherwise given to a private nonprofit corporation rather than stored under the direct control of the BioTrust program or the department of health and human services?

**A So the purpose of the -- the Michigan Department of Health and Human Services does not have the laboratory capacity for management of a Biobank. The amount of freezer space the software that is required to manage individual specimens over a longer of period of time is something that the Michigan Department of Health and Human Services, under the Michigan BioTrust, has obtained through the Michigan Neonatal Biobank.**

Q Okay. Were you involved at all with the creation of the Michigan Neonatal Biobank?

**A No. The Michigan Neonatal Biobank, when I came in to the position -- the first position that I had related to newborn screening, when I came into that position in 2012, the Biobank was already instituted.**

Q Okay. And just to confirm -- forgive me. I know the answer already, but this is my chance to confirm -- is that you don't serve on the board of directors of the Biobank; correct?

**A No, I do not.**

Q Any reason why not?

**A I have a variety of responsibilities at the department. I also am not a laboratorian. And given Dr. Shah's and I's shared responsibilities for the Michigan BioTrust, I'm very fortunate that he was able to take on that role.**

Q How would you describe the nature of the relationship between Michigan Department of Health and Human Services and the Michigan Neonatal Biobank? And I guess let me put it in a clearer parlance than that would be is are they a contract vendor? Are they a partner? Are they another government agency? How is it, in your role as oversight of the dried blood spots that are stored in that facility, do you view the role and the relationship with the Biobank?

**A So the Michigan Neonatal Biobank is not a government agency. We have a contract with the Michigan Neonatal Biobank for the purposes of storage and distribution of the dried blood**

**spots from the Michigan BioTrust. And the Michigan Neonatal Biobank has been a very good partner in terms of, you know, managing those spots, promoting the use of the spots with researchers. So I think they are -- you know, we have a contract with them. They are -- so they have a vendor relationship with us, and they've also been a very good partner in terms of moving this activity along.**

Q Does the Department of Health and Human Services provide monetary compensation to the Biobank for these services?

**A We provide partial support to the Michigan Neonatal Biobank through a contract with Wayne State University. Their Biobank can -- also has an arrangement to be able to cover some other costs related to a fee structure that is charged to researchers. But, yes, the department does provide direct contract support for the activities there at the Biobank. And I think Dr. Shah would -- sorry. Go ahead.**

Q No; no. That's fine. That's fine. And, again, I'm only asking what you know. I'll be asking Dr. Shah a number of questions, as well, given his role as a director on the board of directors of that particular entity when I do his deposition.

**A Uh-huh (affirmative).**

Q I'm only seeking what you know. Do you happen to know how much, as a percentage, or the dollar amount, that the Michigan Department of Health and Human Services pays

ultimately that reaches -- for the operation or the services provided by the Biobank?

**A I'm sorry. I did not come prepared to talk about those numbers today, so I can find that out. There are times where I certainly do hear about the financial support to the Michigan Neonatal Biobank for the functions that are performing a contract but I'm not prepared to speak to those specifics or those numbers today.**

Q Fair enough. That's fair enough. And, again, only what -- I'm only asking you what you know here today as well, so if --

**A Okay.**

Q Well, let me ask this question: I know that as part of the -- I guess -- well, let me make the representation to you that as part each newborn blood draw, the heel prick test that occurs, the hospital charges the newborns a fee for doing that, which is -- again, I don't have the dollar amount that changes year to year, but approximately $130 for that activity. Do you know if all or a portion or none of the monies from those collected fees goes to the Neonatal Biobank?

**A So the majority of those fees go to the Michigan Newborn Screening program. A small amount of those fees have covered some of the costs of the contract with the Michigan Neonatal Biobank. The exact percentage of that, I am not**

**prepared to speak to today.**

Q Okay. I mean, can you confirm, though, it's more than zero but less than all of the money goes to --

**A Oh, yeah. Yeah, that's an easy statement to agree to; yes.**

Q Okay. Very good, very good. Okay. As part of the contractual relationship or the what- -- the nature -- whatever the relationship is between the Department of Health and Human Services and the Michigan Neonatal Biobank, does someone in your role that you serve as -- and, again, I think I just called you the manager of the BioTrust and you identified your relationship with Dr. Shah as part of that oversight authority -- do you have direct control over how the Biobank stores, accesses, uses, and handles the blood spots that are submitted to it under the Michigan BioTrust program?

**A Can you repeat that, please?**

Q Sure. I guess, making it a little simpler. I just want to know if -- say for today that you -- that Dr. -- I mean, Chris over there -- Chris, the manager of the Biobanks, is doing something that you think is inappropriate for the blood spots. It's not in the best interest of the particular blood spots. Do you have the authority to call over there and tell them to change their processes and procedures?

**A Yes. If there was something that was inappropriate going**

**on, absolutely.**

Q And I don't mean this in a legal sense. I'm talking more in either a scientific sense or a project sense. I'm not trying to be inappropriate as in legal or sexual harassment or something of that nature. I'm talking more about the blood spots, the core activities itself. You would have the ability to call or make contact with them and say, "I would like this" -- "you need to start doing it this way," and they would do it that way going forward; is that fair?

**A So the department has procedures that the Biobank is following. We have an understanding what their procedures are. They are in a contractual relationship with us, and we are able to, you know, I don't want to say "direct their operations." I don't mean to imply that we're sort of managing their staff in some way. But in terms of what the procedures for storage, maintenance, and distribution of the dried -- residual dried blood spots, the department is able to direct that. In this case, both Dr. Shah and myself have the ability to reach down to the Biobank regarding, you know, any issue or concern that we have. They're very approachable.**

Q Okay. Very good, very good. And that's what I was looking for. Thank you. So I don't know how to ask this question so bear with me. I asked a little bit earlier about the nature of the BioTrust program, vis-a-vis, the Department of

Health and Human Services. And I'm trying to understand what exactly its nature is. I mean, it's -- you would agree that it's not a division of the Department of Health and Human Services; correct?

**A So the Michigan BioTrust program; you're asking me if it's like an organizational box or a chart? Is that what you're asking?**

Q I'm trying to figure out where it fits in the overall organizational scheme. I mean, it's a division; right? It's not a -- you know, the DHHS has got all its various divisions with various different responsibilities. I just -- I don't know how to describe, or how it would be best to describe where the BioTrust fits into the overall scheme of organizational hierarchy at the department itself.

**A Sure.**

Q Can you articulate that?

**A So we refer to the Michigan BioTrust as a program. Program can be administered between different areas within the organizational structure. So there are aspects of the Michigan BioTrust that are related to epidemiologic questions, which is my organizational structure, epidemiology, and there are aspects of the Michigan BioTrust program that are related to laboratory, which is Dr. Shah's, you know, area of responsibility. So it is a program with the Michigan Department of Health and Human Services that**

**Dr. Shah and I jointly manage.**

Q Okay. All right. Very good. Would you, as part of your role as the -- as part of the role involved with the BioTrust, you would agree -- would you agree with me that prior to 2010 parental consent was never obtained for medical research or at least -- or testing on blood spots for infants born before 2010? Would you agree with that? And I'm talking just on the parents.

**A Let me just check my -- I'm trying to take some notes here to make sure I have my dates correct.**

Q Sure. I believe it's April of 2010, but I know it -- I'm using at least 2010, before that.

(Witness reviews electronic data via video)

**A I'm sorry. It's taking me a minute.**

Q Take your time.

**A So the -- it's smaller, but I can still see it, though. So the -- all right. So there are blood spots that were collected between July 1984 and May 1st, 2010 that may be used for health research under a waiver of informed consent. So we do not have active informed consent for children who were born before May 1st, 2010.**

Q And you indicated that you had some form of consent from something. Could you articulate what that is?

**A So there is a waiver of informed consent that was granted by the Michigan Department of Health and Human Services**

**institutional review board.**

Q Does that -- as the head of the BioTrust program, do you deem that sufficient to be -- let me strike that. As the head of the BioTrust program, do you deem that decision by the IRB to be sufficient to use blood spots for medical research and medical testing of newborn spots before 2010?

**A So the purpose of the waiver of informed consent is for the use of residual dried blood spots for the purposes of research, not for medical testing but for research.**

Q Okay. Fair enough.

**A So, yes, I consider that appropriate.**

Q Okay. Do you have -- I'm sorry.

**A So we have -- we have -- the institutional review board is our human subjects review board. It operates under federal regulations around human subjects, protection of human subjects. And that is the board that I rely on for those kinds of assessments, whether it be related to something like this or other research projects that may come about related to public health data or other -- well, public health data is what I work with.**

Q Okay. Starting in May of 2010, the department -- and this is my representation to you. I want to see if you agree with me. Starting in 2000 -- May of 2010, the department starting to obtain or attempt to obtain some form of consent from parents before utilizing newborn screening -- or excuse

me -- newborn blood spots that remained after the testing was complete under the program. Were you involved at all in any way with the decision to change the policy starting May of 2010?

**A So I was not part of the management structure in the Michigan BioTrust at that point. I was aware, being around the department, of discussions about it, but I was not involved in the decision-making on that.**

Q Okay. Do you know who was the decision-maker on that policy change at that time?

**A I would have to go back and look at that -- for that information. I don't know. I'd have to go back and look for that.**

Q Would it -- okay. I'm sorry. I don't mean to interrupt. Would that be the person that has served in your role as the director of epidemiology at the Department of Health and Human Services?

**A That would be my assumption, but I would have to go back and look at that for that information.**

Q All right. Very good. Starting -- so from May of 2010 forward, without getting into the finer details about what actual consent was obtained, would you, in your role as the -- with supervisory control over the BioTrust, that the consent that the department obtains from parents is sufficient to conduct medical research on the newborn

screenings residual blood spots?

**A Yes. We have created the informed consent process to allow for that -- for a parent to have active consent in the process, yes.**

Q Do you --

**A So did I answer your question?**

Q Yes, you did.

**A I'm not sure if I answered your question or a different one.**

Q No; no. You did; you did. And, please understand, if I'm not saying something correctly or, you know, I'm not -- again, I'm a lawyer not a science person. I have good friends who are, and sometimes the words aren't quite the same. If you can correct me, I'm not above being corrected. My pride will not get in the way, so -- and besides, I'm married. I'm corrected a lot, so there you go.

So the -- you just mentioned about informed consent -- just now was the phrase you just used. Do you, in your role at the department, make a distinction between consent versus informed consent?

**A So we -- when we are doing projects that involve consent, we use a process of informed consent. In the case of Michigan BioTrust, we invested significant time in developing the informed consent brochure for Michigan BioTrust, spent time looking at the informed consent form that goes -- that parents see, try to make those materials as clear as**

**possible. So for the purposes of public health research, I use the term "informed consent" because that is -- the process is to inform people to what they are consenting to.**

Q Do you make a distinction -- setting aside this program just as a public health official, do you make a distinction between getting consent versus informed consent?

**A I'm not sure what getting consent means in your question. The process of what we do is about informed consent that you have provided people with information so that they can make, you know, their informed choice and that they have something to reference back to. So it's something that is common in public health and in public health research.**

Q Okay. You mentioned that you give information so that persons who make informed consent -- who want to give informed consent are so informed; fair?

**A Uh-huh (affirmative).**

Q I'm sorry?

**A Yes; yes.**

Q What information specifically does the BioTrust program provide to parents to give them -- to get them to the point of being informed sufficiently so that they can give their informed consent?

**A So the Michigan BioTrust has a brochure entitled, "After Newborn Screening: Your Baby's Blood Spots." That is -- let me pull it up.**

**(Witness reviews electronic data via video)**

**That is a small brochure that enables -- that provides information about what the BioTrust is, what are risks if your baby's blood spots are used for research, what steps are taken to protect privacy, that we have a certificate of confidentiality. So we have the -- there are -- there are elements of informed consent that are part of the human subject's process, and those elements are covered in that brochure.**

Q Do you believe as the -- in your supervisory role on behalf of the BioTrust, that the information contained in the brochure is a sufficient amount of information for a parent to make informed consent?

**A Yes. We work very hard to ensure that we have the elements that are needed in that brochure. So, yes, I do believe that.**

Q All right. Is there any other processes, procedures, or communications or documents in any way outside of the brochure that is utilized to give parents information so that they have better or equal informed consent? Essentially is there anything other than the brochure that's available to parents at the time of the birth of their child that the department provides them?

**A So the department engages in baby fairs. They provide education to physicians that can be used with expectant**

**parents. We provide education to nursery staff within hospitals so that there is awareness of what this program is. The informed consent brochure, the "After Newborn Screening: Your Baby's Blood Spots," Michigan BioTrust brochure, is meant to be the document the parents can see at the time that they are signing -- that they are, you know, deciding whether or not they want to have -- whether or not they want to consent to the storage of their baby's blood spots.**

**But there are other avenues that we use to promote the program and the existence of the program with social media, baby fairs, education to providers.**

Q I don't want to put words in your mouth but everything you just described would be a phrase I would usually describe as "marketing materials." Would that be a fair statement to cover what you just said?

**A I think it's promotion, education, marketing, you know, we have the baby's blood spot brochure up on our website. You know, with Zoom -- sorry. With the situation that we're all in right now with the epidemic, there aren't baby fairs and things like that. And we've included the brochure and other materials in virtual baby fairs that are going on.**

**So I think, you know, we put materials out, but part of those materials are the actual informed consent brochure, which also includes the information that you would**

**be looking at at the time that you are asked if you would like to participate in the Michigan --**

Q I'm going to make the representation to you that I represent five parents over -- who are the parents of nine children and all of them will testify under oath that none of them received the brochure from the Department of Health and Human Services or any agent thereof.

What steps, if any, does the department take to make sure that a newborn screening -- or excuse me -- that the brochure -- I believe you call it "Your Blood Spots" I believe you called it -- the brochure is provided to parents before they're asked to sign any sort of consent form?

**A So the Michigan Department of Health and Human Services provides education to the nursery staff. We provide the brochure to nursery staff. The card that people are asked to sign is meant to be used in conjunction with the brochure, and that is made very clear in the education. I'm sorry. Just one second.**

Q No problem. Take your time.

**A I'm trying to enlarge something so I can read it to you.**

**(Witness review electronic data via video)**

**And we -- sorry. I shouldn't click and talk at the same time. I apologize.**

Q Take your time. That's no problem.

**A And the form itself that parents are signing, at the top of**

**that form it says, "Before signing this form, please read 'Your Baby's Blood Spots'." It gives details on how small drops of blood collected for the newborn screening may be used in research through the Michigan BioTrust for Health. "If you have questions, please call the Michigan Department of Health and Human Services toll free at" phone number.**

Q As I understand, you're reading from the consent card itself; correct?

A **Correct. So we make sure to reference right at the point that parents are being asked to sign something that this brochure exists. The expectation of the department, the instruction at the department in the provider education materials is that this brochure is provided to parents, you know, so that they are ready when this card comes to them during the baby's stay at the hospital.**

Q Do you have any policies -- written policies, directives or laws, administrative rules or anything that directs when a brochure is supposed to be provided to parents?

A **In terms of the -- there is not a written statute or rule about the timing of that delivery to my knowledge. I would have to go look to see the specific language that is in the -- the education materials that we provide to staff at hospitals regarding that timing. But the purpose and the point of the training regarding active consent is -- that is important as informed consent and that parents have that**

**brochure.**

Q Do you know -- when you mentioned about training, what sort of training does the department provide to the hospital that you're just referencing right there? What kind of training? Like, when does that occur and how does that occur?

**A Sure. So the training occur in a couple different ways. Trainings occur via webinars. Sometimes they occur where staff physically go to a hospital and have a regional in-person training. That's been difficult this year. Obviously we can't do that this year. We also offer training at different conferences that nursery staff may be at. We have a newsletter that goes out to nursery staff and other health providers talking about aspects of the newborn screening program, and we include messages about the Michigan Biotrust in that as well.**

Q Is training mandatory?

**A We are --**

Q That's a "yes" or "no" question. Is it mandatory?

**A I would need to go back and look and see if we use the word "mandatory" when we are speaking to the nurseries. It is expected that staff are trained in this. Whether or not we say this is a mandate that you must take every staff member through, I don't know if we use that word. But it is our expectation that staff who are working a nursery, you know, providing that care directly to parents, are trained about**

**the Michigan BioTrust just as they are trained about the neonatal screening. So, you know, this is -- education about the Michigan BioTrust is being provided alongside education about the neonatal screening.**

Q What steps, if any, does the department take to ensure that --

**A I'm sorry. You may be on mute.**

Q No, I'm not.

**A No? Is it me?**

Q It might be you. We can hear you.

**A Sorry. Can you still hear me?**

Q We can still hear you, yes.

**A I can't hear you. Can you hear me?**

Q Yeah.

**A I'm sorry. I can't hear you.**

MR. ELLISON: Aaron, do you have her phone number or something that you can --

MR. LEVIN: We can get it, yeah. That won't be an issue.

(Off the record)

MR. ELLISON: All right. So just for the record here, we just took a -- we had a small break because of technical difficulties, but we're back on here now.

Q My question -- I'd like to follow up with the question I just asked about is there any administrative rules,

policies, or directives that mandates that training be provided to the appropriate hospital personnel? Meaning everybody that needs to provide a brochure and provide the information does, in fact, do so?

**A Are you -- can you repeat that? I'm sorry.**

Q I guess let me put this into context. Okay?

**A Uh-huh (affirmative).**

Q My son was born in September of 2017 at a hospital in Saginaw, Michigan. The hospital never provided us with a brochure nor provided us with any information until almost 12 hours after his birth. At that point we had, you know, no knowledge or information about the newborn screening program, and the nurse that was there knew very little about the program as well. So the context -- that is my context.

What I'm trying to understand is what steps does the department take to make sure that, for example, the nurse with my son, for example, is sufficiently and properly trained so that they can, A, provide the brochure, and, B, provide sufficient information so that parents like myself and my wife can make informed consent? Can you explain what steps or what guarantees the department provides so that the necessary training is undertaken by these hospital personnel? I think you've been calling them "nursery" employees, but the hospital personnel in some way?

**A Sure. So we provide regular educational sessions with**

**personnel. When -- we also -- we do look at specifics we have about how often our informed consent form is returned blank. We look to see, you know, how often there are -- there, you know, appears to be something about the form that is making clear that there's some sort of lack of clarity or some sort of -- if the form is filled out, you know, in a way that is unclear. We follow back on that as well.**

**We have one-on-one sessions with hospitals where we have concerns about the percentage of forms that are coming back blank or if we have concerns about, you know, complaints that we have received, something like that, about the newborn screening program, or if there's concerns or complaints about Michigan BioTrust itself.**

**We would work with the nursery coordinator and then work to get staff refresher training. For example, we've done sessions where we will have -- you know, our staff will provide multiple sessions to ensure that nursery staff has multiple opportunity within a facility to be able to get trained. We also have repeated reminders that, you know, there are new staff training that is available.**

Q Let me ask this: Do you track whether these employees are, in fact, been properly trained at an individual employee-by-employee level?

**A No. We do not have a record of everyone who is working in a nursery in the state of Michigan. We work with --**

Q Okay. Is the hospital required to keep a record like that?

**A Not to my knowledge, no.**

Q What if a hospital such as -- for example, I'm up in Saginaw. One of our big hospital systems is Covenant Healthcare in Saginaw, Michigan. What if Covenant just said, "You know what? We don't have the time because of COVID right now to deal with any of this stuff. We're not going to do anymore newborn screening blood spot extractions." Can they simply just ignore the department's directive to do so?

**A So in this case you're talking about the newborn screening program, not the Michigan BioTrust program?**

Q Well, let me be clear. I mean, just to make -- let me lay the foundation then. You would agree that the blood spots that go ultimately to the newborn -- or to the Biobank are the residual leftover spots from the newborn screening program; correct?

**A Correct.**

Q Okay. And the newborn screening program blood spots come from the blood extractions done by health professionals at the hospital within -- what? -- the first 36 hours typically of the birth of an infant in a Michigan hospital; correct?

**A Correct; yup. Apart from home births; correct, yeah.**

Q What if a hospital simply just said, "We don't want to participate anymore in your program"? What would happen?

**A So in the case of the Michigan Newborn Screening program, a physician who is overseeing the birth of a child must cause the newborn screening to occur. So that would be, you know, the heel stick -- there's other aspects of newborn screening besides just the heel stick that you are referring to.**

Q I just want to be clear. I only want to focus on the newborn screening. I know there's other tests that are done, hearing and other types of tests, but this case is only about the newborn screening program and the heel prick test.

**A I need to be totally clear with you. Hearing is part of the newborn screening. So what you are referring to is the portion of the newborn screening program that is the dried residual blood spots or the blood spots. So the majority of disorders that are screened for a newborn screening, occur through screening of that blood. But newborn screening also includes screening for hearing and screening for critical congenital heart defects, which are point of care screenings. So that's all part of the newborn screening program.**

Q Okay. Fair enough. So my --

**A So if someone -- so if -- yeah.**

Q I'm sorry. Go ahead.

**A So if a hospital stated, "We're too busy with COVID," I think was your example --**

Q Correct.

**A -- to be able to perform the heel stick portion of the newborn screen, we would be very concerned about that because those babies would be at risk for, you know, more than 55 conditions not being screened for that could cause significant -- could cause loss of life or significant brain damage to that child or other significant irreversible physical harm due to lack of that screen.**

**So that would be taken extremely seriously by the department, and we would be -- I mean, I would be very surprised if a hospital took that step because of the jeopardy that it would put that child in.**

Q What if a parent like myself were to say, "I do not want to participate in the heel prick test at all"? "Do not take my son's blood. Do not do it for a newborn screening test. Do not put it into the neonatal Biobank, no aspect of that portion of the newborn screening program." Is that permissible?

**A So the -- so the state law is on the physician to cause a newborn screen to occur. If a parent was refusing to participate in that, that would be against medical advice. That would be up to the hospital to work through with that parent in that -- that parent in that case.**

Q So the department would not be against Michigan law, as you understand it, for a parent to direct their medical

professional not to perform any aspect of that test?

MR. LEVIN: I'm going to object just to the extent it calls for a legal conclusion.

MR. ELLISON: Noted.

Q Go ahead, Doctor. You can answer.

**A So the law is -- by my epidemiologic training or understanding, the law is directed at the physician, not at the parent.**

Q What if a physician decided, "I'm going to follow the directives of the father," which in the example we've been using would be me, and "I'm not going to conduct that test because it would be contrary to his expressed wishes and directives as the parent of that newborn child"? What steps, if anything, or what trouble could the doctor get in based on following the directive of the parent rather than the department, if any?

**A So state law is where the directive is coming from to the provider. I am assuming what the provider would have to do is to document all the efforts they made to explain to the parent the purpose of the screen, you know, what difficulty the child -- what risk the child is facing if they do have -- they're unfortunate enough to have one of these newborn period disorders.**

**Yes, I think there would be a lot of education and discussion, and then the provider, you know, would have to**

**take it up with their hospital and their legal counsel.**

Q So my question is what would that do from the department's standpoint? What would that do for the doctor, anything?

**A No. The department doesn't have some sort of sanction against the physician in that case. The department does follow up -- so what that would look like to us is that there was a child who did not receive a newborn screening. We routinely look for babies who have had a missed screen. We contact the parents to try and get the child in for a screen. These are children who -- you know, baby can appear beautiful, happy, you know, healthy, all systems go, and two days later completely crash, seize, their heart stops, they go back into the hospital because they have MCAD. Or, for example, a critical congenital heart point of care screen because some children, again, beautiful, happy, great outcome. Baby leaves, turns blue and, you know, has a major heart defect.**

**So these programs are put in place because there are children with these rare disorders who have deaths, disability, brain damage, physical damage because they don't have the screen. So we take missed screens very seriously, and we follow up with the parents, try to explain, again, what the program is about, why it's important. We also -- you know, we want to make sure that the child is connected with a pediatrician or the pediatrician is aware that the**

**child did not have a screen.**

**That way if the child has some kind of symptom, something going on, the physician may have a higher index of suspicion for certain kinds of conditions and be treating -- be attentive to that symptom in a more urgent way than perhaps they would for a baby who has a newborn screening result that came back completely normal.**

Q Okay. The question for you then is part of the informed consent process and when you inform parents of their options in this system, does the department provide them -- provide notice that the parent can completely opt out or otherwise not participate at all in the newborn screening program as it applies to the heel prick test, the newborn screening program, and the Biobank as one big unit?

**A So this is where nomenclature and precision is very important.**

Q Okay.

**A The informed consent is for the Michigan BioTrust.**

Q Okay. Pretend I'm a -- again, we'll use the example of me to use it as an example. When I am presented with a copy of the brochure and the consent card, is the option of me opting out of any part of that program, meaning completely opt out of that program, is that presented as an option to me at the time that this informed consent is being -- is attempting to be obtained from a parent like myself?

**A Can you please be clearer in your question about what you mean by the "program"?**

Q I'm at the hospital. My son has just been born. I, as a parent, do not want to participate in the heel prick test, the newborn screening program, or the Biobank in any way, shape or form. In fact, I don't want you to even conduct the heel prick test because I have an objection to what you guys are doing at the Department of Health and Human Services. Is that option presented and told to me that I have the ability to opt out completely as part of the informed consent process?

MR. LEVIN: I'm going to object to relevance to the extent some of this has been dismissed.

MR. ELLISON: Understood. This is part of a chain, though, obviously, but I understand what you're saying.

Q Go ahead, Doctor.

**A So the Michigan BioTrust consent brochure is presented to the parent along with the informed consent form for the Michigan BioTrust program. That is what the consent is about.**

Q Okay.

**A The consent is not about the medical care in terms of the newborn screening which, in this case, the testing is occurring at the state laboratory. So there is not active**

**consent obtained on behalf of the State of Michigan to the hearing test, the critical congenital heart defect screen, or the heel stick. Whether or not the hospital has some sort of consent to treat form or something like that, or whether those are covered within the consent to treat form that people sign when they come in to the hospital, I don't have knowledge of that.**

Q Looking at the -- I believe earlier you were looking at a consent card in front of you as part of the deposition here today.

**A Yup.**

Q One of the curiosities that I find on this is that there is no option, at least as to my client's time frame when the card was in effect -- at least the version they got in effect, that would actually preclude the department from not storing the sample at all. Simply -- I guess to shortcut this that the sample should be destroyed directly after the newborn screening testing is completed. Why is that not presented as an option to parents?

(Witness reviews electronic data via video)

**A So the card -- sorry. I'm having difficult with my screen.**

Q That's okay. Take your time.

**A So the card states -- so, for example, you can check:**

**"No. My baby's leftover newborn screening blood spots may not be used for health research. By checking this**

**box, you understand blood spots will be stored for up to 100 years but not used for research. The blood spots are stored so the state lab can perform quality control tests and improve newborn screening. You may contact MDHHS if you do not want blood spots stored for any reason after newborn screening."**

Q Do you know what year that particular version of the card has been utilized in?

**A If I can make it big enough.**

Q The reason why I say -- while you're looking, the text you just read to me is not the text that's on the BioTrust card for the infant by the initials RFK in this particular case. That would be signed by Ashley Kanuszewski on 4/22/13. Do you know when those -- I guess what I'm trying to understand, what version of the card you're looking at right now. Is there an indication?

**A So I am looking at the most recent card. I don't know, from what I have here in front of me, when that card went into effect, but we can find that out.**

Q Okay. The reason why -- I also have in front of me a copy -- and this has all been produced pursuant to a subpoena and discovery in this particular case. I'm looking at -- for the same parents, we have child CKK who was born on or about February 10th, 2016 also of Ashley Kanuszewski. That consent card is completely different than the one that

was just simply three years before that. I mean, it's a whole different design completely and none of the text you just read is in that consent card.

**A So --**

Q Do you have any information as to how or why these consent cards have been changed over the years?

**A Sure. So as I mentioned, we work to try and improve how the language is on the card so it can be more understandable. There have also been changes in federal regulations related to informed consent that we needed to incorporate into the card so that the card changes for that reason as well.**

Q What federal regulations have gone into effect that require the change in the card, if you know?

**A So there are -- and I'm sorry. I don't have complete -- I don't have like a detailed time line to refer to here in terms of when those changes occurred and which kind of changes they were. But there have been changes to OHRP regulations as well as changes to the -- I'm going to get the name wrong -- the Federal Newborn Screening Saves Lives Authorization Act.**

**And then again, we also -- you know, we've spent time trying to improve the language on the card to make it simpler to understand, clearer. You've referenced a couple times that I am a scientist, and of course the way I speak, you know, we try very hard to make sure that we're not using**

**scientific terms when we can avoid it, that we're not using, you know, scientific language or that kind of thing in the card so that it is plain language because, you know, that is what makes it an informed consent as opposed to a -- just consent.**

Q Would you --

**A People need to be able to understand what you've written.**

Q Okay. Have you -- I'm on my downward slope here on the last few moments here. So have you, by chance, had the opportunity to read the articles written by my experts in this case, like Dr. Elizabeth Eisenhauer or Dr. Sonia Suter in this case, as part of your preparation today or previously?

**A I do not recall reading an article -- can you -- it was Elizabeth Eisenhauer and Susan --**

Q Susan -- Sonia Suter -- Professor Sonia Suter --

**A Oh, I'm sorry.**

Q -- from George Washington University and Dr. Elizabeth Eisenhauer from Oakland University. She's a professor of nursing. They've done studies about the understanding and consent by patients -- well, excuse me. I should be clear. Dr. Eisenhauer has done studies about the knowledge of parents who are providing consent at the time of birth. Have you seen her article at all?

**A I don't recall that I have seen her article. It has been**

**awhile since I've read the materials that came in the original filing.**

Q Okay. And also -- I also was just curious if you've read the article written by Professor Sonia Suter. She's a bioethicist. She's actually a law professor writing about informed consent, about Michigan's informed consent system. Did you have a chance to read and have a comment on her article?

**A I do not have a comment today on her article. I do not recall reading it. It doesn't mean I haven't. It's been quite a long year in terms of COVID.**

Q Fair enough. And I get -- and by the way, I know you guys have been busy, busy, busy with COVID, and as a member of the public, I'm very grateful for the work you guys have been doing. So -- all right. So, finally, just a couple last follow-up questions for you. Harry Hawkins, I believe is someone who worked underneath -- correct me if I'm wrong -- worked underneath you. He's since passed obviously. Did he work underneath you as part of your supervisory chain?

**A No. Dr. Hawkins worked in the laboratory in a very --**

Q Would that be Dr. Shah?

**A Yes.**

Q Okay. All right. Can you also confirm that the information that's extracted by the newborn screening program is stored

in the system that we call the "central registry"? You're looking confused.

**A Can you ask that again? Sorry. Yeah.**

Q The reason why I ask is -- so let me give a little bigger, broader context here so we can communicate effectively. My understanding is if someone like a researcher -- pretend I'm a researcher now rather than -- I've been using me as a parent. Pretend I'm a researcher at a university, and I want to get ahold of everyone, and I saw -- for example, on the video that you guys have on your website, a study was done about mercury levels for pregnant women around Lake Superior, for example.

**A Uh-huh (affirmative).**

Q And I wanted to get blood samples from everyone who is -- I want to get blood samples from the Biobank that's people from particular zip codes during a particular time frame. That information, as I understand it, is stored in the system called a "central registry." Am I right or am I wrong about that?

**A I'm not sure what database you're referring to.**

Q Okay. So the term "central registry," that's not ringing anything for you right now?

**A The Department of Health and Human Services has registries for -- like we have a cancer registry. There's a -- some aspects of the birth certificate are referred to as a**

**registry at different points when the birth certificate is being managed. But I'm not quite sure what you mean in relation to newborn screening data.**

Q Okay. Let me ask it this way. Let's clear that off the table and ask it this way: Pretend I'm a researcher that wants to do research on mercury levels of pregnant women around Lake Superior State University -- or around Lake Superior up in the Upper Peninsula. I want to find blood samples during a particular time frame with particular zip codes up in the Upper Peninsula. How would I go about getting that information -- or how would I go about getting those blood samples that would be responsive to that categorization or that narrowing of samples that I'm looking for? How will I go about doing that?

**A Yup. So you would contact the department. You would provide a protocol as -- you know, with that kind of detail in it in terms of, "I need women who delivered to -- you know, were born to women who lived in these areas during these time periods." We would -- for example, Mary Klein or some of her staff might have a conversation with a researcher trying to understand more about what they are looking for so that we can help them tailor that ask.**

**Very often researchers -- you know, you may want to know where the mother was living at the time of -- you know, before they became pregnant. We don't have**

information on that. So we just talk to the researcher. You know, we can identify children in terms of the zip code that they lived in that's on their birth certificate. That's the zip code that their residence was -- their mother's residence was at time of birth.

So they would have their written protocol. They would also fill out a human subject review form, the IRB application. Their protocol, their IRB application would be reviewed by the human subjects review board. It would also be reviewed by the scientific advisory board that's part of the BioTrust. So there would be three reviewers with different kinds of expertise who would look at that application in a blinded manner -- pardon me. And they would provide information -- they would rate those applications. They'd provide their opinion and their score back to the department.

If the application passes that point, depending on the other kinds of information that might -- that the researcher might be looking for, there may be other steps. So, for example, if you -- you may have to go through a science advisory board that vital records has. That might be another step that your application will go through. But let's pretend it didn't have to go through that one. You have gone through the human subjects review at the -- at MDHHS. You would have gone through scientific advisory

board review at MDHHS. You would have gone through human subjects review at your own institution as a researcher, and at that point the information that you'd be looking for would be prepared. So there would be -- staff would go through and identify the children who we are able to pull under that request -- you know, their records and their session number.

Epidemiologists would gather the data, like I'm assuming you want mother's age or, you know, how many births she's had or something -- thinking about that research question, but, you know, whatever it is that has been agreed upon. Oh, there's one other document that -- there's two other documents that you would go through. You would also have a data use agreement because you were using data for certain purposes. You can't use data -- it's not like we're just giving you data and you have ownership over it. You're getting it for certain purposes. And there would also be a material transfer agreement that covers the residual dried blood spots.

Once all of those -- and the data use agreement would be reviewed by our compliance and privacy office. Once all of that paperwork, protocols, and forms have been reviewed and approved, the accession number for the children that met the inclusion criteria for that study would be sent down to Michigan Biobank -- Neonatal Biobank.

That's the only thing they'd know is that accession number. They would look to find those spots. They would process however number of punches of those spots were needed.

We would provide -- because there is data in this case, we would provide the limited data set with that accession number, and that would be provided to the researcher and then the blood spots would be provided to the researcher with -- sorry. Let me back up. I said something wrong there. We provide the accession number and limited data to the Biobank. They put that together with the dried blood spots for that individual and then they give it a totally different number.

So the Biobank doesn't know who the child is or the mom. The researcher doesn't know who the child is or the mom. If the researcher calls my staff -- they have a study ID attached to that sample and the data that they received. If they called my staff and said, "I'm looking at sample such and such and blah, blah, blah, I want to know more about this person," I don't know who that person is.

So it is -- we have -- you know, one of the reasons why the Michigan Neonatal Biobank is important is that, you know, my staff don't hold the key between the identity of this person that the materials are about and the researcher. Sorry. That was a lot of information. That was (inaudible) a long time there.

Q No; no. You're saying exactly what I need. You're confirming a lot of the details that I understood and come to learn about the program. So I guess my -- I guess the point I was trying to make with all this, it is possible to associate certain identifying criteria to a particular blood sample, meaning zip code, mother's age, you know, what number you were in birth, to a particular blood sample that's being stored at the Biobank, subject to all those details that you just provided just now?

**A It is possible to provide a researcher with a very limited set of information about a family. And we spend a lot of time working with researchers to -- for example, we would not give mother's age. We would give age group. So we spend a lot of time limiting the amount of information or thinking through, you know, how little information -- and, quite frankly, how little information can we give to this researcher where they can still accomplish their goal and provided that goal is in, you know, alignment with the community values advisory board, the scientific advisory board, you know, all of those principles and review steps there.**

Q Okay.

**A So you wouldn't get a blood spot that says, you know, "This is from a 35-year-old mother from," you know, "2004 births at zip code such and such." You know, that would not**

**happen.**

Q Let me ask this then: You mentioned now when a researcher wants to get access to a blood sample, they've got to get approval through, for lack of a better word, your office, IRB, the privacy office, the keying and re-keying of those. After all that, does the department ever go back to the parent and get their consent or back to the individual, if they're over the age of 18, and get their consent to participate in a blood study? Whether or not -- I don't want to differentiate right now, because I will in a moment, between prior -- May of 2010 and after May of 2010?

**A The department does not go back to parents whose child is part of a study. We're relying on informed consent or the waiver of informed consent that exists associated with that blood spot. A parent can -- or an adult whose blood spot is in our system, can put in a form to remove their informed consent to remove their samples from this process and/or to have their spots destroyed.**

Q I know, but my question, though, is that when studies get -- when the study is -- after checking through all those offices and all those different steps, the department does not go back and ask either the parent, if the child is still a minor, or the person's blood spot itself for consent to participate in that particular study; correct?

**A Correct; correct.**

Q And before May of 2010, there was no written consent obtained by the parent for medical research for -- say for -- say, for example, a 2004 sample was to be provided from one of these studies, for example, no parental consent was obtained at that point directly; correct?

**A Correct.**

Q All right. And then the reason -- and the basis for that would have been the waiver of informed consent by the IRB board?

**A Correct.**

Q After 2010, does the department take any steps, once a child is born, they sign this consent form, does the department in any way go back after a certain amount of time and say, "Hey, your sample is subject to medical research activities. Do you wish to continue to provide us with consent?" Do you ever go back and re-up or renew consent at any point?

**A No, we do not.**

Q Any reason why not?

**A There's two thoughts in response to that question. We have obtained informed consent for use of a sample of materials, that is someone's, you know, intention at that time. So we make use of that informed consent going forward. We do not have a record of where that person has gone, you know, where -- where that person is now. We do not have a mechanism for reaching back out to that individual. That**

**would be a very large undertaking to reach back to 100,000 people a year, for example, let's say.**

Q Okay. Let me ask this question, too, is that obviously when a child is born, they are not in a capacity to make a decision like that as a one or two-day old child. You would agree with that; fair?

**A Sometimes I wonder about my own daughter, but, yes, I agree.**

Q True, true. Okay. You would, at no point, though, when a person becomes the age of majority, which in Michigan is the age of 18, that the department doesn't go back and confirm that they -- the actual person themselves wishes to continue to be part of a potential research study or studies going forward?

**A Correct. We do not do that.**

Q Any reason why not?

**A We have not had resources to be able to do that. Again, the -- that would be, you know, 100,000 people a year that we are reaching back out to for re-consent, I think.**

Q But if you were to use a sample that the person today -- say just today -- you had a researcher today, and the person was -- the sample being used of somebody who is now 30 years old, you would not be reaching out to that 30-year-old person to say, "We want to use your sample now even though your parent, who is not you, gave some form of consent back 30 years prior on the day you were born"? You don't do

anything like that; correct?

**A No, we do not. We do not.**

Q All right. Last question I have is -- all right. I guess I'm going to skip over that. I'm going to skip over that part. I want to follow up with -- we didn't start in the beginning, so we jumped right off. If you could actually give your name for the record, as we jumped right into starting into this before. If you give your name for the record?

**A I was wondering, yes.**

Q Yeah.

**A So my name is Dr. Sarah Lyon-Callo. I'm the director of the Bureau of Epidemiology and Population Health. Currently I am also working out of class as the director of the Bureau of Infectious Disease Prevention. I have a --**

Q That wouldn't have something to do with the COVID, would it?

**A Just a little. Dr. Shah and I are pretty much all COVID seven days a week. I have a Ph.D. and a master's degree in epidemiology. I have been working with the department officially as a civil servant since 2001. Prior to that I worked with the department as a contractor from fall of 1998. And I was the director of the Division of Lifecourse Epidemiology and Genomics with the newborn screening follow-up program beginning in 2012. I think that's everything you need from me, but happy to answer anything**

**else.**

Q I think so.

MR. ELLISON: At a minimum here, I appreciate your time today and working with the communications between scientist and lawyer, which is always -- not always apples to apples in communication. I appreciate your time. And on a personal note, I do appreciate all the hard work you guys have been doing down with COVID because I know you guys have been on -- very much involved. And part of the reason we've delayed these depositions as long as we have, is we want to keep you guys working on that.

THE WITNESS: Yeah.

MR. ELLISON: As we often thank our veterans, I'm also going to thank our scientists, so we appreciate your work helping us all out, the rest of us over here who are hiding in our holes. So we appreciate it.

THE WITNESS: Well, thank you, Mr. Ellison. I really -- thank you very much for saying that. Thank you,.

MR. ELLISON: Well, I was going to say nobody thanks a lawyer, I can tell you that, but I'm going to thank a scientist for sure.

THE WITNESS: I have to admit I have seen -- yeah.

MR. ELLISON: Anyway, thank you for your time today. I'm going to turn it back over. These two other gentleman might have some questions for you, but I'm done

for today. So thank you for your time.

THE WITNESS: Okay. Thank you.

MR. LEVIN: Jeremy, do you have anything? Do you want to go first?

MR. KENNEDY: I do have some, yes. Good afternoon, Doctor. My name is Jeremy Kennedy. I'm the attorney for the -- actually at this point Dr. Antonio Yancey.

MR. ELLISON: Jeremy, I'm going to step away out of screen. I can still hear you, but I'm just going to step off the camera but keep going.

MR. KENNEDY: Okay. Thank you.

EXAMINATION

BY MR. KENNEDY:

Q Doctor, you distinguished, I think rightfully so, between the BioTrust and the Biobank; correct?

**A Correct.**

**(Mr. Hendricks exited deposition)**

Q The Biobank, does that do anything other than store the dried blood spot cards, to your knowledge?

**A So the Biobank stores, maintains, you know, records about how many spots are on the stores so they sort of curate them in addition to keeping them nice and cold. And they also, upon the direction of the Michigan Department of Health and Human Services, distribute spots. So they'll assign the**

**study-specific number to a spot and provide that and then distribute that spot out to the researcher at the director -- direction of Michigan Department of Health and Human Services. The Michigan Neonatal Biobank will also promote the existence of this resource to researchers as well.**

Q They do not, however, approve research projects, to your knowledge?

**A No, they do not.**

Q And they do not select the dried blood spots that are sent to researchers; correct?

**A Correct.**

Q The only -- the Michigan Department of Health and Human Services directs them to provide certain dried blood spot cards to researchers and that is all the information they get; correct?

**A I'm sorry. Can you repeat that?**

Q When there is a -- when they are -- when they do provide dried blood spot cards to researchers, they -- the information the Biobank gets is simply, as I understand it, "Pull these particular blood spot cards and send them to this entity"; correct?

**A So the Biobank will be instructed to find the cards with certain accession numbers -- ascension -- accession numbers. It will be directed how any punches of the card out of a**

**dried blood spot need to be provided -- these little 13 millimeter punches. And in some cases they may also be given a limited set of variables, information that needs to be sent with that dried blood spot.**

Q Okay. When they get a -- when they get a dried blood spot card from Health and Human Services for storage purposes, the card is de-identified; correct?

**A Correct.**

Q It just has an accession number that allows DHS to locate the card to say, "These are the cards we need if it comes up in the future"?

**A Correct. Yeah, the name, date of birth, all that is ripped off the card before it is sent down to the Michigan Neonatal Biobank.**

Q Okay. And the BioTrust program, can you just explain briefly what that does, the difference between the two?

**A So the Michigan BioTrust -- let me just make sure.**

**(Witness reviews data via video)**

**The Michigan BioTrust is a program that receives the use of the residual dried blood spots in health research. The BioTrust itself includes outreach community engagement activity policy development around guiding principles about what's an appropriate use of the spots. The BioTrust also has coordination and approvals of research proposals -- or disapprovals of research proposals requesting use of the**

**dried blood spots. The Biobank is solely responsible for storage and maintenance of the spots and then distribution at the direction of the Michigan Department of Health and Human Services.**

Q And, Doctor, you're familiar with the underlying policies behind the storage of the dried blood spot cards after their initial screening; would that be fair?

**A Yes.**

Q Okay. Why does the State of Michigan Department of Health and Human Services store these dried blood spot cards after they do the initial newborn screening for the disease -- various diseases?

**A So the BioTrust for Health was put into place because there was recognition that there was this population-based set of residual sample that could be a very valuable resource for research into questions of public interest and questions for public good. So, I think, in the earlier questioning there was a comment about -- or a hypothetical about looking at mercury exposure to mothers in certain areas of the state and what sort of mercury exposure those babies may have had. It's a very important resource for understanding exposures and conditions that babies were in during one of the most sensitive periods of development in terms of gestation.**

Q So would it be fair to say that, generally speaking, the purposes of storing the dried blood spot cards is you are

looking for ways to protect the public health? Would that be accurate, broadly speaking?

**A Yes, that would be accurate.**

Q And part of the reason you store these cards, again, in broad terms, is to at least in part develop tests for additional screenings of newborns if there are additional conditions, diseases that can be detected in the initial screening? You can discover those as well?

**A Yes. This resources is something that can be used to identify -- to aid in the development of new tests for new disorders. Or I should put it -- it's not a new disorder. It's disorders. Let me be clear. It's an important resource for being able to -- for researchers to be able to develop new tests that would enable the detection of severe disorders of the newborn period through the newborn screening process or other medical processes at time of birth.**

Q And in your opinion, Doctor, is that an important thing for the state to be able to do to develop these new tests for existing conditions?

**A Yes, very important.**

Q And why is that?

**A So there are more than 54 conditions that we screen for in newborn -- in the newborn screening program. The program saves children's lives. This program also prevents disease**

and disability in children. You know, I remember when we had the 50th anniversary for the newborn screening, being moved by meeting a young man who had galactosemia, and he -- if he had not been identified as having galactosemia, he would have been, you know, considered failure to thrive. He would not be as physically robust or mentally robust as he was. And, you know, he came and spoke about what is he doing now.

I've also had the fortune to work with a gentleman who was diagnosed in newborn screening with PKU, which is a disorder where his body is unable to process a particular (inaudible). What happens to people with PKU is that because they are unable to appropriately process that aminoacid, which is one of the basic building blocks of proteins in all of our bodies, they build up toxins and they lose mental capacity and other kinds of capacities. So before -- this is one of the first conditions we were able to screen for in newborn screening. And before there was a test for that and the ability for people to avoid eating this particular aminoacid, children would, again, be born healthy, beautiful, bright, you know, a wonderful moment, and then begin to deteriorate and eventually end up with significant loss of cognitive function, being unable to function, you know, independently in society.

This particular gentleman who I was able to work

**with has now just graduated from medical school. So, you know, when I see those moments about how valuable this program has been, it certainly drives us all forward to see what else we can do to prevent disease, disability, and mortality among children.**

**We just recently went through a -- we've added a number of conditions just recently around lysosomal storage disorders and a couple of other disorders, one that's called X-linked adrenoleukodystrophy. And there's frequently mothers or families -- you know, one of the things I love about my job is I get to meet so many very dedicated parents.**

THE WITNESS: As you are, Mr. Ellison, as well.

**A And, you know, this was a mother who had lost her son to X-linked adrenoleukodystrophy. And we've just recently been able to begin screening for that. You know, we have lysosomal storage disorders where we have families who -- you know, they've lost their first child to this disorder. And their next child, they're able to know that the child may have this disease because their earlier child, as families will say, has been sacrificed.**

**So newborn screening enables families to know about disorders that may run in their families and prevent that, you know, loss of life -- very painful loss of life.**

**You know, we have treatments like for sickle cell**

**disease where children are able to take low dose antibiotic prophylaxis in their first year of life. It used to be that one-third of babies born with sickle cell disease were dead before their first birthday. And because of newborn screening, the -- you know, we don't see children dying due to sickle cell -- due to infections in sickle cell disease in their first year of life. I'm sorry. I could go on for quite for awhile. I'm very passionate about protecting children.**

Q No. That's a wonderful answer, and my commentary -- it sounds like it's very rewarding work. And I don't think -- from what it sounded like, it sounds like you literally -- this testing saves thousands of lives quite literally?

**A Yeah. We could calculate the number for you. I don't have that off the top of my head right now.**

Q That won't be necessary.

**A Okay.**

Q And there are, as I understand, a number of polices in place to protect the privacy of the individuals whose DBS cards, the dried blood spot cards, are sent to the Biobank and possibly used for research later; is that correct?

**A Yes.**

Q Are there any -- in addition to the accession number, any other policies DHS has put in place to protect the privacy of these individuals?

**A So the review process that we have, in terms of human subjects, in terms of scientific advisory board, the data use agreement process, are all designed to protect privacy in terms of if a researcher is going to use these dried blood spots. Is that what you're asking me --**

Q Yes.

**A -- or are you referring to something about the Biobank itself?**

Q No. I'm referring to any polices DHS has, not Biobank policies.

**A Thank you.**

Q And there are policies in place where a parent or a subject, you know, once they reach the age of majority, can request that the dried blood spot cards be destroyed; correct?

**A Correct.**

Q And does that request go to DHS directly?

**A Yes. It goes to the Michigan Department of Health and Human Services. There is a form. There's need for identification, you know, driver's license, birth certificate, so that we're assuring that the person who is requesting destruction has the ability to do so and that we've got the right material as well.**

Q Okay. And once the information is received and the request to destroy a card is confirmed by DHS, can you walk me through the -- how the cards are destroyed? What the

process is to have the card destroyed?

**A Do you mean in terms of the -- after the approval has been done? The actual process of destruction?**

Q Yeah. After they get (inaudible) the request --

**A Okay. That --**

Q -- you look at everything, confirm that everything is proper, and that the card should be destroyed, what happens at that point?

**A So the follow-up -- the epidemiology side of the Michigan BioTrust folks who work with me usually handle the paperwork and making -- you know, making sure that everything is in there and that the request has gone up to compliance and legal for review. At the point that it is approved, we then send off to the laboratory for destruction. So I think that answer is probably better heard from Dr. Shah than me.**

Q Okay. To your knowledge -- and if this is something that's best asked for Dr. Shah, that's fine -- after the card is destroyed, does DHS keep any of the information that would have been contained on the card?

**A The Michigan Department of Health and Human Services will still retain the information on the child and what their newborn screening result was. So it is the dried blood spot card that is destroyed.**

MR. KENNEDY: Okay. Thank you, Doctor. I have nothing further.

MR. LEVIN: I have just a couple of questions for you, and then --

EXAMINATION

BY MR. LEVIN:

Q Yeah. So we've talked a lot about -- or at the start of your deposition, talked a lot about use and control of these residual dried blood spots, but who owns these residual dried blood spots?

**A So the Michigan Department of Health and Human Services has qualified ownership over the dried blood spots. Sorry. Let me grab my notes because I do better with my notes.**

**(Witness reviews data via video)**

**Yeah, so the Michigan Department of Health and Human Services is who has qualified ownership of the dried blood spots while they are in storage. The department may, you know, release part or all of residual dried blood spot to the individual and that may be -- like an individual may request their -- or their family may request their dried blood spots for use in research studies or other uses of -- or destruction.**

**So the individual retains control over that, but the department has the qualified ownership of it. The Michigan Neonatal Biobank does not have ownership over those spots, qualified or otherwise.**

Q So is that why a parent or an individual after they turn 18,

can request destruction of those blood spots?

**A Yes.**

Q And then relatedly, can a parent or an individual after they turn 18, request the return of those residual dried blood spots?

**A Yes, they can.**

Q So we talked a lot -- or you talked a lot also about the educational materials and information provided to -- I'm going to say hospitals and medical professionals. Who is responsible ultimately for providing that information to new parents?

**A The medical professional treating that -- that -- the medical professional that is attending that birth I guess is the way I would put that -- treating that baby and mother.**

MR. LEVIN: That is all I have. Thank you.

THE WITNESS: Thank you.

MR. ELLISON: I've got just a couple follow-ups here, and then I think you're all done for today. And I appreciate your time.

EXAMINATION

BY MR. ELLISON:

Q You mentioned just a minute ago about return of blood spots. Is it possible rather than getting blood spots destroyed, that you can get blood spots returned to the parents or to the person if they're over the age of 18?

**A Yes, they can. The -- say, for example, there has been an instance in my memory where an individual or parent -- I can't remember which -- wanted the dried blood spots used in a research study, you know, not associated with the department or the Michigan BioTrust, a separate study, and, you know, requested that the spots be sent to that -- returned to the parent or adult -- I can't remember which -- but went to that researcher.**

Q If I was a parent and wanted my child's blood spots returned to me -- just returned to me, not for another study, just I don't want you guys to hang on -- I don't want the Biobank to hang on to them anymore, would the department return those blood spots to me as their parent?

**A If you've gone through the process of, you know, identifying that, you know, who you are, that you are, you know, related to that spot, yes, the department can return those to you.**

Q Is that information ever given to a parent that they have the option to have the return of their child's blood spots, to your knowledge?

**A I would have to read through the brochure. I don't think it is covered in the brochure that you can have them returned to you. This is something that -- you know, the information about destruction is covered in there. At the point where people are asking about destruction, that is, people want them returned, other times people will be aware that the**

**resource exists and (inaudible) for a different purpose and will reach out about that as well.**

Q Have you ever heard of a -- have you ever heard of a use of the blood spots beyond -- well, I guess let me ask it this way: Rather than doing a medical study that blood spots have been used for crime victim identification?

A **So that is not part of the Michigan BioTrust for Health. That is a use of the blood spots that predates Michigan BioTrust for Health. It's part of the newborn screening program. So, yes. I'm sorry. That was a long way to say "yes."**

Q Okay. So if a law enforcement individual wanted to get access for a blood spot for, let's say, DNA testing -- right? -- the department has got some sort of process or standards in place by which they'd give that blood spot to a law enforcement officer?

A **Correct. There is a process -- there is a legal process that they would have to go through. It's not just that someone calls up and says that they're a policeman, they want the blood spot. There is a legal process that they would have to go through. You have to meet a standard that this is for crime victims so this -- it can be released for that purpose.**

Q Okay. Do you guys have any written policies or directives on this? This is something that I've not seen as existing,

at least to date. I mean, is there some sort of policy somewhere or something that references this?

**A I do not have those things up in front of me. I did not review or prep for this kind of question right here. So, yes, but I can't describe them to you.**

Q You didn't prepare for this portion of the deposition?

**A No.**

Q If you would, could you get -- when you get done -- and this doesn't have to be done in the next ten minutes after we're done here. But just in the next couple of days, can you get a copy of that over to Mr. Levin? Because I'm going to request that as part of discovery request in this case. Okay?

The last thing I wanted to ask is is that the -- do you know, as a general custom or practice, when hospitals typically ask for consent for retention and use of medical -- the remaining medical -- or excuse me. Let me start over again. Sometimes I get tongue-tied when I'm talking here. Are you aware of the usual customary time frame of when the hospitals ask for consent from parents to use the residual blood spots for medical research? Like when is that consent sought?

**A Are you asking when hospitals usually obtain Michigan BioTrust consent?**

Q No, not Bio- --

**A Or are you asking --**

Q When the --

**A Because they don't have residual dried blood spots.**

Q Okay. Let me rephrase the question and make sure we're clear. For example, I'll just use me as the example. My son was born at 3:30 in the afternoon. The following morning at 6:00 a.m. after a whole night of no sleep and birth of a child, they presented me, an exhausted dad, and a sleeping mother, with a consent card for signature. Is it the usual practice of hospitals, based on your knowledge, that hospitals ask for consent after the birth of the child but before they discharge from the hospital?

**A So I'm not sure what consent you would be talking about in terms of the hospital practice.**

Q Well, let me -- the consent card that's in front of you that checked the box "yes" or "no." The one that we've been talking about.

**A Uh-huh (affirmative).**

Q That was presented to me after 12 hours of no -- more than 12 hours of no sleep and my wife -- after my wife just gave birth to our son; right? And this is my representation. Obviously you weren't there. I acknowledge that. As well as I will also represent that to my clients, each one of them were at different hospitals, were presented with their cards almost about 12 hours following the birth of their

child. Do you know if that's the usual customary practice or the standard practice required by the department when seeking consent for putting these blood spots -- or deciding what to do with these blood spots for medical research purposes?

(Mr. Hendricks joins deposition)

(Ms. Campbell leaves deposition)

**A Okay. So now I understand what your question is is you're asking about what a usual practice -- am I aware if there's a usual training of the presentation of the informed consent brochure and presentation of the card. Okay. So I wasn't sure if you were talking about like some sort of residual tissues or something that the hospital deals with in a different way. But I'm hearing that you're asking about Michigan BioTrust.**

**So the neonatal blood sample, there is a period of time after the baby is born. There is sort of a window after the baby is born that it's important to draw that sample. And, you know, if you draw the sample too early -- so a lot of what is being detected for in newborn screening are different metabolites that the baby has generated in their blood and they have to find this window of time where there's enough time that the baby will have generated those metabolites that can be screened for but not too much time that the information is no longer useful in terms of being**

**able to identify newborn screening disorders in a timely manner to protect that child.**

**So that's why this 12 hours. So 12 to 24 hours is the period of time that you want to have that blood drawn for that baby. Length of stay for a healthy -- a lucky, healthy baby in the hospital is around 24 to 48 hours, so there's a lot that is being managed and packed in in terms of that child's care during that time. So 12 to 24 hours is when they want that sample drawn.**

**In terms of -- you know, I am not a neonatal nurse, but in terms of how they're functioning, they're going to want to handle everything about that newborn screening card, including the Michigan BioTrust consent, which is in the newborn screening card, even though it's not part of the newborn screening program, and they're going to want to, you know, manage all of that information, those asks, at the same time.**

Q Well, let me ask you --

**A So I think it's not surprising to me that it's around that 12-hour time for the parents that you know.**

Q But let me ask this, though. If a parent -- if you truly wanted a parent to understand the risks and benefits of this program, meaning whether it's -- and I would actually say both, but we're here specifically about the neonatal Biobank storage and use of medical researchable blood, wouldn't it

make sense to require that hospitals need to give these two or three weeks out before the parents show up at the birth rather than in the aftermath of right after the birth occurred?

**A So about one-third of the births in the state are not preregistered at hospitals prior to delivery. That said, we encourage hospitals to provide information in baby packets. We work with OB/GYN's and other groups to promote awareness of, like, what to expect. So we promote the information about newborn screening but also about the Michigan BioTrust to health care providers so that they can provide that to patients.**

Q But there's no rule requiring that, though; correct?

**A No.**

MR. ELLISON: Thank you very much. Again, appreciate your time today.

MR. LEVIN: I have just one follow-up briefly.

EXAMINATION

BY MR. LEVINE:

Q So if somebody submits a consent form -- strike that. I'm going to rephrase. If a parent signs a form providing informed consent to the BioTrust program in storage and research and medical projects, can they change their mind later?

**A Yes.**

MR. LEVIN: Thank you.

MR. ELLISON: Jeremy, I guess you get last shot. Have you got anything else you want to ask?

MR. KENNEDY: I have nothing further, no.

MR. ELLISON: Before this poor lady's cell phone battery goes dead here? All right. Doctor, thank you so much today for your time. You've been a good sport working through all of this craziness with the Zoom platform here. So we're all set with you.

(Deposition concluded at 3:06 p.m.)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 24

## Deposition of Adam Kanuszewski

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v Case No. 18-cv-10472

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, HON. THOMAS L. LUDINGTON
MAG. PATRICIA T. MORRIS

Defendants.

/

# VIDEO CONFERENCE DEPOSITION OF ADAM KANUSZEWSKI

Taken by the Defendant MDHHS on the 23rd day of October, 2020, via Zoom, at 1:30 p.m.

APPEARANCES:

| | |
|---|---|
| For the Plaintiffs: | MR. PHILIP LEE ELLISON (P74117)<br>Outside Legal Counsel PLC<br>PO Box 107<br>Hemlock, Michigan 48626<br>(989) 642-0055 |
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| For the Defendant Michigan Neonatal BioBank and Antonio Yancey: | MR. JEREMY C. KENNEDY (P64821)<br>Pear Sperling Eggan & Daniels PC<br>24 Frank Lloyd Wright Drive, Suite D2000<br>Domino's Farms<br>Ann Arbor, Michigan 48105<br>(734) 665-4441 |

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Via Zoom Video Conference

Friday, October 23, 2020 - 1:31 p.m.

MR. LEVIN: All right. Actually, just very quickly, how would you like us to pronounce your last name?

MR. KANUSZEWSKI: Kanuszewski (pronouncing).

MR. LEVIN: Kanuszewski. Thank you.

MR. KANUSZEWSKI: Uh-huh (affirmative).

MR. LEVIN: So I am Aaron Levin. I work at the Attorney General's office. I am the attorney representing Director Gordon, Dr. Shah, Dr. Lyon-Callo, and Mary Klein. It's my understanding that you're an attorney; is that correct?

MR. KANUSZEWSKI: Yes.

MR. LEVIN: So you know how depositions work. I won't bore you with all of that. If you have any questions, feel free to ask. If you need me to re-ask or you don't understand the question, please let me know. If you don't remember, that is a perfectly acceptable answer. If you hear "objection," we will -- you generally proceed to answer, or we'll stop you, depending on the objection. But I think you know all of that. So I will dive right in.

REPORTER: Do you solemnly swear or affirm that the testimony you're about to give shall be the whole truth?

MR. KANUSZEWSKI: Yes.

ADAM KANUSZEWSKI

having been called by the Defendant MDHHS and sworn:

EXAMINATION

BY MR. LEVIN:

Q So this lawsuit is regarding --

MR. ELLISON: I'll stop you real quick. Just to make sure on the record that, because we're doing this via Zoom, and I know there's some different rules with this, we have no objection to this being conducted via Zoom, even though we're not all in the same room. So go ahead, Aaron.

MR. LEVIN: Thank you. I appreciate that.

Q So diving in, this lawsuit is relating to the continued retention and possible research uses of residual dried blood spots. What concerns do you have about the Department of Health and Human Services retaining those residual dried blood spots?

**A I never knew anything about it.**

Q I'm sorry. I think we lost connection for a moment there.

**A I didn't know anything about it.**

Q Now that you do, do you have any other concerns?

**A Yes.**

Q What are they?

**A I don't know what they're being used for, who they're being given to, and quite frankly, whenever I deal with the government and stuff, I don't think they should be taking**

**things without asking permission.**

Q Have you done any independent research about the program?

**A I have not.**

Q When did you learn about the program?

**A When I talked to Phil.**

Q Do you remember when that was, ballpark?

**A Without looking, I don't. I'd be guessing at a date.**

Q Do you remember what year it was?

**A Probably two years ago, but that's purely a guess. I mean, somebody could refresh my memory with something.**

Q Do you remember if it was about the time the lawsuit was filed?

**A Yeah. It was right previously before the lawsuit was filed. I don't even recall when the lawsuit was filed, to be honest with you.**

Q Fair enough. Do you have any reason to believe that your children's blood spots have been accessed?

**A No.**

Q Do you have any reason to believe they've been used for research?

**A No.**

Q Do you have any reason to believe these blood spots have been sold?

**A No.**

Q What are you hoping happens to these residual dried blood

spots at the conclusion of this lawsuit?

**A I've never really put a lot of thought into that to be honest with you. I guess I'd want them returned to me.**

Q Are you aware that you may direct the Department of Health and Human Services to destroy your children's blood spots at any time?

**A No.**

MR. LEVIN: All right. I am going to share my screen and I will mark this and send it around, or I'll send it around, at least, at the conclusion. It's the same exhibit we looked at this morning for counsel.

(Deposition Exhibit A marked)

(Counsel shares document via video)

MR. LEVIN: All right. Can you all see that?

MR. ELLISON: Yes.

MR. LEVIN: Is the whole form visible or do I need to zoom it out?

MR. ELLISON: You've got to zoom it out. It's all crunched up.

MR. LEVIN: All right. One moment. There we go.

MR. ELLISON: That's pretty good right there.

MR. LEVIN: Can you read it?

MR. ELLISON: I can see the whole thing as one big document. You might have to -- I don't know if Adam can see it, but I can see it fine. I'm on a computer, though.

THE WITNESS: I'm on my phone. I can pull my computer, but if I strain I can see it. Do you want to give me a minute to read it?

MR. LEVIN: Yeah. Do you want -- would it help if I zoomed in?

THE WITNESS: Well, if you zoom in, you're going to have to scroll up and down as I read it. Just give me a second.

MR. LEVIN: Okay.

(Witness reviews exhibit)

**A All right. I read it.**

Q Have you seen this form before?

**A No.**

Q Having reviewed it, would you agree that it allows you to request or direct the Department of Health and Human Services to destroy your children's blood spots?

MR. ELLISON: I'm going to place an objection. I know this is going to sound kind of silly. Recognizing Mr. Kanuszewski is an attorney, he is being called as a lay witness. So I object to the fact that he's being asked to render a legal opinion. But, Adam, go ahead.

**A It appears I have some options as to, yeah, what I want done with the blood that's in their possession.**

Q Does the first one say "destroy all remaining blood spots?"

**A It says that, and it says, "I understand that by checking**

**this box, no blood spots will be available for any future use, including medical, identification, or research purposes." Does that mean that they were being used for medical, identification, or research purposes?**

Q I'll show you another exhibit in a moment. Let me finish with this one. But having read the form, is this something you'd be willing to sign?

**A I'd probably consult legal counsel first.**

Q Fair enough.

MR. LEVIN: All right. So I am going to share another exhibit.

MR. ELLISON: Do you want to give that one a letter or a number? How do you want to do that?

MR. LEVIN: Oh, so, yeah. That first one will be A, and then this next one I will mark as B and send around at the conclusion as well.

MR. ELLISON: Okay.

MR. LEVIN: So this will be B.

(Deposition Exhibit B marked)

(Witness shares document via video)

Q Can you see that?

**A No. You'd have to blow it up a little bit.**

Q All right. How's that?

**A Yeah, I can see it. I'm going to try to -- I can read it. Hold on a second.**

Q This one is actually three pages, so let me know, and I will scroll so you can see all the pages.

**A Okay. I read it.**

Q Okay. This is page two. I think it's the same as page one. I'm not entirely --

**A It appears to be the same.**

Q All right. So page three is different. And I will review my notes as to why that happened. But here's page three.

**A Okay.**

**(Witness reviews exhibit)**

**Okay. I read it.**

Q Does that appear to be your wife's signature at the bottom?

**A It looks like it.**

Q Do you have any reason to believe it's not?

**A No.**

Q All right.

**A Can you scroll up to the other one? The one you showed me first?**

Q Yeah, how's that?

**A Yeah. So I think the first two pages were the same; right?**

Q I believe so. I think that's just an oversight on my part.

**A Because I was just looking at the years. It looks like the first one would have been -- okay -- for one kid. And then -- okay. All right. They're not together, is what I'm saying. They're dated years apart, so that's not like one**

**document. That's like two documents -- two documents.**

Q I know, I --

**A Yeah, okay.**

Q Yes, that's correct. I've put them in one --

**A It's misleading. I was going to say it's misleading when it's given to you as, like, one document because I think the years were different is all.**

Q Yeah. The years are. It's just -- I put them in one document thinking they'd be easier to review, but -- do you need more time to review it, or are you satisfied?

**A No, I looked at it. I'm fine.**

Q So looking at this first one, is it fair to say that, "Yes, my baby's blood spots may be used for health research," is checked?

**A It is checked.**

Q So based on this form and referring to only this form, do you have any reason to believe that the state has used your baby's blood spots contrary to your express wishes or the family's express wishes?

**A Well, my signature is not on there, but, I mean, it appears my wife's is.**

Q All right. I'm going to go now to the third page, which is the different one. Same question. Do you have any reason to believe that the state has done anything contrary to this form?

**A Will you rephrase that, please?**

Q Yes. And if you need to take a moment to review the form, that is all right, too. So the form looks a little bit different, but it is also a consent form for use of blood spots in research. Do you have any reason to believe that the -- the Department of Health and Human Services has acted contrary to the permissions described in this form?

MR. ELLISON: Objection. Now, that calls for a legal conclusion, and I also object to the statement at the beginning of that as to lack of foundation. Go ahead.

Q If you need to review the form, take all the time you need.

MR. ELLISON: I was objecting on the basis of your recitation of what this form is, but, go ahead.

**A So rephrase it so I make sure I give you the right "yes" or "no" answer here.**

Q And I apologize. It's starting to storm here. So if the mic picks that up --

**A No, that's all right.**

Q -- or interference, I will be back as soon as I can.

**A Did you ask me if I had any reason to believe that the state used the blood in any form contrary to this form? Is that what you said?**

Q Yeah. And I will rephrase if that's not clear. Would you like me to rephrase?

**A Yes, please. I was waiting.**

Q Oh, sorry. All right. So towards the -- there's that box in the middle.

**A Uh-huh (affirmative).**

Q And towards the bottom there's a sentence that starts, "I voluntary agree"?

**A Yes.**

Q So I'm going to read that box. So that box says, "I voluntarily agree to allow my chid's dried blood spots" -- it's abbreviated but dried blood spots -- "to possibly used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening."

**A Correct.**

Q Do you have any reason to believe that the state has acted contrary to that paragraph and in this document?

**A No; no.**

Q Do you recall if you were ever given an educational pamphlet or brochure explaining the newborn screening program?

**A I don't.**

Q Do you recall if you were ever given an educational pamphlet or brochure explaining that retained blood spots may be used for medical research?

**A I don't.**

Q Did you review your files at home and determine if you had any documents related to this program?

**A I didn't specifically scour the house or anything. I don't really have files at home. I mean, I have a strong box with some legal documents. It's certainly not in there.**

MR. LEVIN: Just one second. I think that may be all I have. That's all I have right now.

MR. ELLISON: Jeremy, do you want to go next?

MR. KENNEDY: Yes.

MR. ELLISON: Yup, all right.

MR. KENNEDY: Good morning (sic), Mr. Kanuszewski. My name is Jeremy Kennedy. I'm the attorney for Dr. Antonio Yancey and Michigan Neonatal Biobank.

THE WITNESS: Good afternoon.

EXAMINATION

BY MR. KENNEDY:

Q So you are the parent of -- I believe you have three children who are plaintiff's in this case; is that correct?

**A I'm the biological father of two of them, but I consider myself a parent to all three, yes.**

Q Okay. So one would be a stepchild?

**A Correct.**

Q Okay. And the two that you're the biological father of, were you present when they were born?

**A I was.**

Q You were in the room with your wife?

**A I was.**

Q With the births of the youngest -- or I'm sorry, -- the older of your two biological children, was it natural birth or C-section?

**A C-section.**

Q Did she have an epidural, to your recollection?

**A I don't recall.**

Q Was she ever unconscious as far as you can recall?

**A I don't think so.**

Q What was the date of your oldest child's birth?

**A My oldest biological child?**

Q Yes. Sorry.

**A It would have been -- he's April 22nd of '13.**

Q Do you remember what time of day?

**A Morning, I believe.**

Q Okay. And you said that looking at Exhibit B on the third page with -- you said you believe that's your wife's signature?

**A I do.**

Q As far as you can tell?

**A Yeah.**

Q Do you recall what time of day that form was signed?

**A I don't remember that form being signed.**

Q Okay. And I'm sorry. They said that I'm sleep deprived right now. Did you say after the C-section -- was your wife ever unconscious for any amount of time from the medication?

**A I don't recall. I don't -- I mean, outside of sleeping, I mean, -- I mean, I don't -- well, I guess you'd have to narrow it down to, like, a time frame. So after she had the birth, when are you asking?**

Q (Inaudible)

**A Well, of course, she slept. I mean, yeah, she was unconscious at times. I mean, we were there for, I think, a couple days.**

Q Other than sleeping?

**A I don't think so.**

Q Okay. You said the first time you became aware of this -- of these -- backup. Are you aware of anything about the Michigan Neonatal Biobank prior to this case? Let me ask you a different --

**A I don't -- yeah, please.**

Q Prior to this case, have you ever heard of the Michigan Neonatal Biobank?

**A No, I don't think so.**

Q All right. Are you aware of anything about how the biobank operates?

**A Not really. I mean, I know there's some blood samples stored now. But outside of that, no, not really.**

Q And prior to this case being filed or initial -- we'll say initial investigation, you had no awareness of how it operated; correct?

**A Correct.**

Q And you had no awareness of how the biobank is funded?

**A No.**

Q Okay. And do you have -- do you have any personal knowledge of how the dried blood spot cards are used?

**A No.**

Q Do you have any personal firsthand knowledge that any of your children, biological or otherwise, whether their cards -- their blood spots cards are even being used for anything?

**A I don't.**

Q So, therefore, you also do not have any evidence that the dried blood spot cards are being used contrary to any authorization that may have been given?

**A Correct.**

MR. ELLISON: Objection. Asked for a legal conclusion, but go ahead and answer.

**A Correct. I answered.**

THE WITNESS: Did you guys hear it?

MR. ELLISON: Yeah.

MR. KENNEDY: Yes, thank you.

THE WITNESS: Oh, yeah.

MR. ELLISON: Jeremy has got a new one that just came along, so he hasn't been sleeping too much the last couple days here, so --

Q This is true. He will be two weeks old tomorrow, so I'm still getting him up.

**A Did you get presented your forms?**

Q I did.

**A Okay.**

Q I did. So have you ever requested that the dried blood spot card of any of your children be destroyed?

**A I have not.**

Q Are you aware of any of the possible uses of the dried blood spot cards that are being stored?

**A No.**

Q Are there any uses of those cards that you would consider acceptable?

**A I don't think so.**

Q In your opinion, is it acceptable for the blood spots to be taken to test for congenital or chronic diseases under the program?

**A That's kind of an odd question.**

Q Okay. Let me --

**A That's saying -- well, it's like you're inferring that if I had given them permission to take them. I mean, I would say, yeah, that would be appropriate if I said, "Yeah, take them." But, I mean, I think the issue is, like, not knowing that they were taking them. I mean, once you have them, if I said you could use them, then, yeah, sure.**

Q That's not what I'm asking. You are aware that they take the five or six spots of blood to -- initially to test for -- I believe the current number is 56 chronic conditions, diseases. Are you aware of that?

**A No.**

Q So you have no knowledge of what the blood spots are taken for whatsoever?

**A To be honest, no.**

Q Okay. Prior to this lawsuit being filed, did you, in any way, investigate the use of the dried blood spot cards?

**A No.**

Q Now, is it your position that the taking of the dried blood spot cards in any way interferes with your ability to direct medical care for any of your children?

**A Could you rephrase that, please?**

Q Do you believe that taking the dried blood spot cards in any way interferes with your ability to determine how to care for your child medically?

**A No. Do I -- I think I understand what you're saying. It's kind of a long question. I think it breaks up in between. Do I think that them -- rephrase it one more time. I believe the answer is no. I'm trying to draw the -- go ahead.**

Q Let me see if I can ask it simpler, and I know that's not always my strong point. Have you ever felt that your

ability to determine the medical care for your child has been impacted by the taking of the dried blood spot card?

**A No.**

Q Do you feel like your ability to determine medical care for any of your children has been impacted by the storage of the dried blood spot cards?

**A No.**

Q And you have, I believe you said, no personal knowledge whether the dried blood spot cards had been used for any purpose at all; correct?

**A Correct.**

Q If you were not aware before, you are aware now that there is a form that you can fill out to request the destruction of the blood spot cards; correct?

**A I just read it, yes.**

MR. KENNEDY: I have nothing further.

MR. ELLISON: Okay. I have a few questions for you here.

EXAMINATION

BY MR. ELLISON:

Q I'm going to refer to your three children by their first initials because of the federal privacy laws with minors.

**A That's fine.**

Q Okay. And, fortunately, you've got three children with three different initials, so that helps.

**A Yes.**

Q As for -- and I'm going to call them "infant." I know some of them aren't infants anymore with their age now, but to Infant R and Infant C, that's -- those are your two biological children?

**A They are.**

Q Yup. And Infant D is the child -- the biological child of your wife; correct?

**A Correct.**

Q Are you the legal guardian for Infant D?

**A To be actually honest, I don't know exactly. I mean, yeah; yeah.**

Q Let me ask you this. Have you adopted as --

**A No; no.**

Q Okay. All right. And I don't mean to be passing judgment on parenting or that nature. It's just the legal nature of these sorts of things, so --

**A Yeah. And I guess when you say "legal guardian," I guess I don't know the actual definition of legal guardian. I mean, he resides here full-time. I mean, my wife and I raise him. He still has contact with his biological father. His biological father is still involved in his life. So maybe that gives you a better picture of that.**

Q Okay. Very good. For your two biological children, did anyone from the State of Michigan or any of its agents,

including even a doctor, talk to you beforehand about the risks versus the benefits of conducting any sort of blood tests as it applies to the newborn screening program?

**A I don't believe so.**

Q Has anybody -- at the time that the blood samples -- well, let me ask this. Did you know that either one of your two biological children -- did you know or were told that blood samples were being taken from your child for testing by agents of the State of Michigan?

MR. LEVIN: I'm going to object to relevance and to the conclusion that the doctors are agents.

MR. ELLISON: Fair enough.

Q Go ahead.

**A No; no.**

Q All right. Did anyone tell you that they were going to be taking blood samples for your two biological children prior to them extracting the blood?

**A No.**

Q After the blood was taken, did anyone talk to you about the risks, benefits, basically being informed about what the purpose and goals were to taking those blood samples?

**A No.**

Q Did anyone tell you where they were taking those blood samples and what they were doing with them?

**A No.**

Q Did they tell you who was going to be in possession of them and from what basis they were going to be retained for?

**A No.**

Q Did anyone at any time talk to you, be it from the state, an agent of the state, or someone from the biobank, talk to you about the blood samples being transferred from where they were being tested to the nonprofit Michigan Neonatal Biobank?

**A No.**

Q Did anyone discuss with you and explain the benefits and risks of storing either one of your two biological children's blood samples in the newborn -- or, excuse me -- in the Michigan Neonatal Biobank?

**A No.**

Q Has anyone spoken to you or otherwise explained to you about what sort of legal protections or what sort of privacy protections the blood samples have while in the Michigan Neonatal Biobank?

**A No.**

Q As you've come to learn through this lawsuit, you have learned that your two children's -- your two biological children's blood samples are, in fact, in the Michigan Neonatal Biobank; correct?

**A Correct.**

Q Would you, if you had known at the time that the blood

samples were going to be indefinitely stored without your permission ahead of time, would you have given consent?

MR. KENNEDY: Objection; calls for speculation.

**A Do you want me to answer, Phil?**

Q Yes, please. Yes, please.

**A I don't think so without researching it a little bit, you know. I would want to know what would be -- I would just want -- I'd want to know more. I still want to know more.**

Q Did anyone present you before, during, or after the blood being extracted from your two biological children, any sort of paperwork or pamphlets about anything, aspect of the newborn screening program, including the storage at the neonatal biobank?

**A Not that I recall.**

Q Do you have any concerns about -- today, as I was just saying, the biobank -- I'll make the representation to you that your two biological children's blood samples, including their DNA and medical data about what's contained within those blood samples, are being stored at the Michigan Neonatal Biobank. Do you have any concerns about that material and that information being stored at the biobank?

**A Yes.**

Q What kind of concerns do you have?

**A Well, I don't feel it belongs to them. I feel that that's mine, my wife's, our kids genetic biological information. I**

**don't want it out there being bought, sold, used or whatever. And I don't even know if that's a thing, but it certainly is a concern of mine that someone else has control of it and basically didn't tell us anything about it.**

Q Okay. Looking at -- on your screen right now, this is a copy of Infant R, the form in that respect. Is there any reference on here to the Michigan Neonatal Biobank?

**A I don't see any.**

Q Okay. Have you provided -- to your knowledge, have you or your wife provided any authorization to transfer your two biological children's blood samples to the Michigan Neonatal Biobank?

**A No.**

Q Have you given any authorization for them to -- the Michigan Neonatal Biobank -- to sell, convey, give or otherwise allow third parties like researchers to use that blood sample from the biobank?

**A No; no.**

Q Do you have any concerns about your children's medical privacy today with the way the blood samples are currently housed and stored?

**A Yes.**

Q Okay. What are those?

**A I don't even know how they're housed or stored.**

Q Would you agree that the lack of information and lack of

knowledge would -- strike that. Let me ask it this way.

**A That's actually -- that's the scary part, I mean, is the lack of knowledge of what's going on and what could be done. I mean, I don't know if the scare, the threat, is real, not real. I mean, I just know that somebody has ahold of that stuff and something is being done with it, and to what extent, I don't know and I was never told.**

Q Okay. Is that the concern that you have with this lawsuit is the fact that someone else has your son's -- your two biological sons' medical and DNA data without you having any control or say over that material?

**A Yes.**

Q As for Infant D, which was not your biological child, were you present for his birth at all?

**A Was not.**

Q Now knowing what you know now about the biobank and the newborn screening program, would you, in fact, have provided consent to store your blood samples indefinitely with the Michigan Neonatal Biobank?

**A No.**

MR. ELLISON: I have no further questions.

MR. LEVIN: I have a couple just briefly.

EXAMINATION

BY MR. LEVIN:

Q Prior to filing the lawsuit, did you do any independent

research about the newborn screening program or the biobank?

**A No.**

Q Have you done any since?

**A No.**

Q How much would you say you know about these programs?

**A Not much.**

Q Did you ever investigate if there was a means of having the blood spots destroyed, other than filing a lawsuit?

**A No.**

Q Do you know how long the actual screening process takes?

**A No.**

MR. LEVIN: That's all I have.

MR. ELLISON: Jeremy, do you want anything else?

MR. KENNEDY: I actually just want to circle back.

EXAMINATION

BY MR. KENNEDY:

Q I forgot to ask, your youngest child, was that a natural birth or a C-section?

**A C-section.**

Q I assumed as much, but want to make sure. And similar to the question about your older biological child, was your wife given any kind of anesthesia, epidural, anything like that?

**A I don't know. I couldn't be for certain.**

Q Okay. And other than sleeping, was she ever unconscious any

time as a result of drugs or other --

**A You know, she being -- I thought about that after you asked, and I think with C it's more possible. I want to say that she lost a lot of blood and that she was away from us for quite some time. I think that with the youngest would be, if I'm not mistaken. So it's possible, but I wasn't -- I didn't see it. So she'd be able to tell you.**

MR. KENNEDY: Okay. That's all I have.

MR. ELLISON: Okay. We reserve the balance of our questions for trial. Adam, you're all set, and you can log off.

THE WITNESS: All right. Thanks.

MR. LEVIN: Thank you.

(Deposition concluded at 2:10 p.m.)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 25

## Deposition of Ashley Kanuszewski

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v Case No. 18-cv-10472

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, HON. THOMAS L. LUDINGTON
MAG. PATRICIA T. MORRIS

Defendants.

/

# VIDEO CONFERENCE DEPOSITION OF ASHLEY KANUSZEWSKI

Taken by the Defendant MDHHS on the 23rd day of October, 2020, via Zoom, at 3:30 p.m.

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Via Zoom Video Conference

Friday, October 23, 2020 - 3:35 p.m.

MR. ELLISON: And I'll just jump in here right off the bat and say we consent to the Zoom deposition in this case, and we waive any objection as to doing this deposition by Zoom.

MR. LEVIN: Thank you. I was going to ask off the top this time so you --

MR. ELLISON: Oh, there you go. There you go. Well, I'll shut up and get out of the way then. Go ahead.

MR. LEVIN: Not a problem. All right. So my name is Aaron Levin. I am Assistant Attorney General. I'm representing Director Gordon, Dr. Lyon-Callo, Dr. Shah, and Mary Klein in this case. I don't know if you've done a deposition before, but bear with me just for a moment. We are recording. There will be a transcript, so if we can do our best not to talk over each other, that makes a clean transcript and keeps everybody happy and not mad at me.

If you don't know the answer to something or you don't remember, those are both perfectly acceptable answers. If you need me to rephrase, or anybody who is asking a question -- because I think we're all going to ask some -- that's perfectly fine. Just let us know. I'm going to, I anticipate, show you a couple exhibits. If you need me to zoom in or my screen sharing is not showing that correctly,

let me know. I'll get that adjusted.

If at any point when somebody is asking a question, you hear somebody object, in all likelihood you'll continue to answer the question, or we'll stop you if it's one you shouldn't. But there may be some objections, and we'll just try not to talk over each other and we'll get that all squared away. And if you need a question repeated, we can do that.

MS. KANUSZEWSKI: All right.

MR. LEVIN: So with that, I am going to dive in unless you have any preliminary matters. Anybody else?

MR. ELLISON: No, go for it.

REPORTER: Do you solemnly swear or affirm that the testimony you're about to give shall be the whole truth?

MS. KANUSZEWSKI: Yes.

ASHLEY KANUSZEWSKI

having been called by the Defendant MDHHS and sworn:

EXAMINATION

BY MR. LEVIN:

Q All right. So as it relates to this lawsuit, it's regarding the Department of Health and Human Services retention of residual dried blood spots. What concerns do you have about the department retaining those residual dried blood spots?

**A Not fully knowing what's happening with them, and that I didn't really know what -- that they were taking them**

**completely or what it was for exactly.**

Q Prior to this lawsuit, did you do any research about the newborn screening program?

**A No.**

Q Prior to this lawsuit did you do any research regarding the retention and for possible research uses of the dried blood spots?

**A No.**

Q Have you done any independent research about either of those things after filing the lawsuit?

**A No.**

Q Do you have any reason to believe that your children's blood spots have been accessed?

**A Do I have reason to believe they've been accessed?**

Q Correct.

**A Yes, now.**

Q What's that?

**A I guess I'm not completely understanding your question. If you could repeat, rephrase it.**

Q Sure. Sure.

MR. ELLISON: I think -- Aaron, I don't mean to jump in, but I think she might be thinking blood from the heel as opposed to blood from the blood bank.

MR. LEVIN: Okay. So, I can clarify that.

Q So as it relates to the stored blood spots post screening --

so there's the initial screening process and then there is storage for research purposes after that first screening. As it relates to those stored blood spots, do you have any reason to believe -- and I'm going to ask the question the same way, but if that didn't clear it up -- do you have any reason to believe that those retained blood spots have been accessed or used?

**A I guess not, no, I don't know.**

Q Do you have any reason to believe those blood spots have been sold?

**A No.**

Q What are you hoping happens to the blood spots at the conclusion of this lawsuit?

**A That they're given back or taken away from anybody who maybe shouldn't have them without my permission.**

Q I am going to -- are you aware that at any time you may direct the Department of Health and Human Services to destroy the blood spots?

**A No.**

Q Would the destruction of the blood spots address your concerns in this case?

**A Yeah. As long as they -- yeah, from everywhere that they're -- but I don't know they're supposed to be, you know. Yes, I would -- if they were destroyed completely, then I guess that would, yes.**

MR. LEVIN: I'm going to share my screen and show you what we will mark as Exhibit A.

(Counsel shares document via video)

(Deposition Exhibit A marked)

Q All right. Can you see that?

**A Yeah, mostly. It's kind of small.**

Q All right. I will -- did that help any?

**A Yeah. Yeah, I can see.**

Q All right. If you could just take a moment and review this form and let me know when you're done and let me know if you need me to zoom in or zoom out or scroll up or down. Or let me know when you've read it and if you need me to move the screen so that you can read it.

(Witness reviews exhibit)

**A Okay.**

Q Have you ever seen this form before?

**A No.**

Q Having had the chance to review it, does it provide the opportunity to have the blood spots destroyed?

MR. ELLISON: Objection; calls for a legal conclusion, but go ahead, Ashley.

**A Can you repeat your question one more time?**

Q Sure. So noting the objection and that that will stand as I ask it, having reviewed the form, does this form allow you to direct the Department of Health and Human Services to

have residual dried blood spots destroyed?

**A** **It looks like it.**

Q Are you willing to sign this form?

**A** **I don't know. That would be something I'd want to discuss with an attorney or my husband or --**

Q Fair enough.

MR. LEVIN: That's all I'm going to need on this screen. If you'll bear with me just a moment, I am going to share my screen again and show what we'll mark as Exhibit B. So this is two pages. Each page is a different document. I just marked them together because I thought it would be easier to share them that way.

(Counsel shares document via video)

(Deposition Exhibit B marked)

Q Can you see it?

**A** **Yes.**

Q And is this one big enough, small enough, or too small?

**A** **Yeah, I can read it. It's fine.**

Q All right. If you could let me know when you're done with the first page, and then I will scroll to the second page.

(Witness reviews exhibit)

**A** **Yup.**

Q Now if you could review the second page, please.

**A** **Okay.**

Q Do you recognize either of these?

**A No. I mean, I recognize my signature. That's about it.**

Q So that is your signature on both forms?

**A Yes.**

Q All right. So I've now scrolled back to the first page. Fair to say that the checkbox next to, "Yes, my baby's blood spots may be used for health research" is checked?

**A Yes.**

Q Now, I'm going to scroll back to the second page. Does that box in the middle -- towards the bottom of that box in the middle, it says, "I voluntarily agree to allow my child's DBS" -- which stands for dried blood spots -- "to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening"; is that correct?

**A Yes.**

Q And is that your signature on this form?

**A Yes.**

Q Do you have any reason to believe that your children's dried blood spots are being used contrary to the expressed statements in these two documents?

**A I guess not, no, after I read it now.**

Q Do you recall if you were ever given an educational pamphlet or brochure explaining the newborn screening program?

**A No.**

Q Do you recall if you were ever given an educational pamphlet

or brochure explaining that retained blood spots may be used for medical research?

**A No.**

Q When did you learn about the newborn screening program?

**A Not since this was happening. I don't remember anything about it. I don't -- this -- the dates show the days my kids were born, so I think that was the first time I'd ever heard of it.**

Q After that time, did you ever do any independent -- I already asked that. Strike that.

MR. ELLISON: I'll give -- I think she's kind of confused on your question, so go ahead and dig into it. I don't mind.

MR. LEVIN: Right.

Q So not withstanding these forms, when do you recall learning about the newborn screening program?

**A I don't ever recall learning about it.**

Q Are you familiar with it now?

**A Now that I've read this that you've shown me, a little bit. I'm only familiar what I'm reading that you're showing me in these pages right here.**

Q Is it fair to say you were familiar with the newborn screening program at some point prior to your filing a lawsuit?

**A Not really, no. I mean, what -- well, yes. I mean, I guess**

**I don't know -- I guess I'm confused at, like you said -- or like Phil said, what exactly you're asking me. Do I know anything about this screening program? No. Did I learn a little bit about it through this process? Yes.**

Q When was -- so you said you learned a little bit about it. When was that, to the best of your memory?

**A In speaking with my attorney. I don't know when that was exactly.**

Q Do you think it was shortly before filing the lawsuit?

**A Yes.**

Q Thank you. Was it about that same time you think you learned about the retention program and possible research uses?

**A Yes.**

Q Did you ever do any research to determine if you could have the residual dried blood spots destroyed by means other than filing a lawsuit?

**A No.**

Q Do you know now that there is a method?

MR. ELLISON: Objection; calls for a legal conclusion. Go ahead, Ashley, you can answer if you can.

**A Say that -- repeat it, please.**

Q To the best of your knowledge right now, is it possible for you to request that the blood spots be destroyed outside of this lawsuit?

MR. ELLISON: Same objection.

**A I don't know.**

Q So I'm going to re-share my screen again and go back to Exhibit A.

(Counsel shares document via video)

So we reviewed this form a few minutes ago; correct?

**A Yes, uh-huh.**

Q And at that time you indicated that the form appears to allow for destruction of the blood spots; correct?

**A Yes; yes.**

Q You are aware now that there is a method for you to request destruction of blood spots?

**A Yes; yes.**

MR. ELLISON: Objection; calls for a legal conclusion. Go ahead, Ashley, if you can answer.

**A Yes.**

Q One moment. Sorry.

MR. ELLISON: No, take your time. That's fine.

Q During this lawsuit, did you ever review any paperwork you may have relating to the newborn screening program, or do you have any? Let me rephrase that. Have you had an opportunity to review your paperwork at home or wherever -- I'm going to ask that again. Do you have any paperwork relating to the newborn screening program?

**A No.**

Q Do you have any paperwork relating to the retention and storage, possible research uses of dried blood spots?

**A No.**

MR. LEVIN: I don't have anything further right now.

MR. KENNEDY: All right. Good afternoon, Ms. Kanuszewski, my name is Jeremy Kennedy. I'm the attorney for Dr. Antonio Yancey, Michigan Neonatal Biobank, the parties in this lawsuit.

EXAMINATION

BY MR. KENNEDY:

Q So you have never -- have you ever requested that your children's dried blood spot cards be destroyed?

**A No.**

Q Okay. And that Exhibit A that we've been talking about, assuming that it is as Mr. Levin has represented and a form that would allow you to request the cards be destroyed, we're going to start with that assumption that it is as he's represented. I understand that your attorney has raised an objection. If you requested the destruction of the dried blood spots for your children using that card, do you have any reason to believe they would not be destroyed?

**A I don't know.**

Q Why not? Is it you don't know because you think you fill out a form with the state, and they'll ignore it?

**A I guess, like I said, I would like to review it further. From what it says, no, I guess I would not have any reason to believe that. They should do what I sign.**

Q And I'm not saying you have to make that conclusion. I'm saying if we accept that it is as represented and you ask for them to destroy it, you don't think there's any reason they wouldn't destroy it?

**A No.**

Q Now, do you know prior to this lawsuit did you -- had you ever heard of the Michigan Neonatal Biobank?

**A No.**

Q Since this lawsuit has started, have you learned anything about the operation of the Michigan Neonatal Biobank?

MR. ELLISON: I'm going to -- Ashley, we're going to put an objection here, and I want to direct you anything that I've told you as part of our discussions is covered by attorney/client privilege. Outside of what I've told you, you can answer any other information anywhere else. Okay?

THE WITNESS: Yes.

Q Not looking at anything that Mr. Ellison has told you, just any knowledge you've had on your own, any research you've done on your own, anything like that?

**A No.**

Q So you have no awareness how the biobank operates?

**A No.**

Q You have no personal knowledge of what it does?
**A No.**
Q You have no personal knowledge of how it is funded; correct?
**A No.**
Q Do you have any evidence that the biobank is using any of your children's dried blood spot cards in any manner?
**A No.**
Q It's not even that you -- strike that question. I'll withdraw what I was about to ask. So prior to this lawsuit being filed, did you do any research about the use of the dried blood spot cards?
**A No.**
Q Did you have any knowledge of how dried blood spot cards, whether they were your children's dried blood spot cards or any other dried blood spot cards, what they were used for?
**A No.**
Q And you have no reason to believe the cards for your children have ever been used; correct?
**A Repeat that again. What did you say?**
Q Do you have any reason -- I'm going to rephrase. Do you have any reason to believe that your children's dried blood spot cards have ever been used?
**A No.**
Q Do you have any reason to believe that your children's dried blood spot cards have ever been accessed for any purpose?

**A No.**

Q Do you have any reason to believe that any of the information contained in your children's dried blood spot cards has ever been sold to anyone?

**A No.**

Q Do you feel that the fact that these dried blood spot cards -- your children's dried blood spot cards being stored has in any way interfered with your ability to determine medical care for your children?

**A No.**

Q Now, when Mr. Levin was asking you some of his initial questions about what you knew about the cards, you said, I believe, you didn't know why they were taking the blood spots completely. Did I hear that correctly, first of all?

**A Say that again?**

Q Let me ask it a different way. That seems to be confusing even to me, and I just asked the question. So you have three minor children who are plaintiffs in this lawsuit; correct?

**A Uh-huh (affirmative).**

Q Yes?

**A Yes.**

MR. ELLISON: You've got to say "yes" or "no." Yup, there you go.

**A Yes.**

Q Okay. And when we deposed your husband earlier, he said that the two youngest children were born via C-section; correct?

**A Yes.**

Q Your oldest child, was that a C-section, or was that a natural birth?

**A Natural.**

Q Okay. And when all three of your children -- actually, we're going to -- the two youngest children, the middle child -- when your middle child was born for the C-section, were you given any sort of epidural or anesthetic?

**A Yes, epidural.**

Q And were you at any point during that procedure unconscious because of the medication?

**A No.**

Q And when your youngest child was born, were you given an anesthetic or an epidural?

Q Epidural.

Q And at any point during that procedure were you ever unconscious?

**A No.**

Q Now, Exhibit B, you indicated your signature on the two forms -- on the authorization forms; correct?

**A Yes.**

Q Do you remember signing those forms?

**A No.**

Q Do you remember anything at all about those forms? When you received them, for example, whether they were given to you? Anything at all about that?

**A No.**

Q Okay. Do you recall when you were in the hospital -- when your -- any of your children were born, any medical professional actually taking the heel prick, the blood samples from the children?

**A Not particularly, no. I don't remember that.**

Q So you don't recall --

**A I know they took -- pricked the heel of my oldest son, I remember, because he had complications at birth. I do remember that, but I don't remember any other heel pricking.**

Q Do you remember --

**A And one had jaundice. They pricked his heel for that. That's the only time I remember that.**

MR. ELLISON: Ashley, we should have mentioned -- we didn't mention with you, just because we're in federal court, we've got rules about referencing children's names. If you could just use their first letter of their name, we can reference whichever of your three kids.

THE WITNESS: Okay.

MR. ELLISON: And we all know their names, but we've got to do that for purposes of the record. Okay?

THE WITNESS: Okay.

MR. ELLISON: Okay. Thanks.

Q So other than what you've just mentioned, do you recall them -- anybody in the hospital mentioning anything about why blood would be taken?

**A No.**

Q Okay. Did you ever object to anyone drawing blood from any of your children while you were in the hospital?

**A I don't know.**

Q Now, you didn't know anything about the dried blood spot program before this suit was filed. You didn't know anything about the storage of the dried blood spot cards, I believe is what you testified. Why did you then decide to file suit?

**A It was brought to my attention what they were doing with the blood samples, and my husband came to me about this and asked if -- you know, I guess we discussed it together. My husband is the one who brought it up to me first.**

Q What specifically was brought to your attention that made you decide to sue?

**A That --**

MR. ELLISON: Wait, wait, wait. I also want to direct you again to the extent it's not me, though. Okay? Does that make sense? What I told you is covered by attorney/client privilege, but you can testify to everything

else that you were told. Okay?

THE WITNESS: Okay.

MR. ELLISON: Weird rules, I know, but go ahead.

**A So you want to know when -- what made me decide to do this is the question?**

Q You indicated you found out -- I think what you said was how -- what they were doing with the dried blood spot cards.

**A My husband told me that they were being taken from the blood bank -- like to use for other things beyond maybe -- I don't really know. Being sold, I guess, is what my husband told me. And I don't even really understand what was happening with them, but he -- I remember just awhile ago when he brought this to my attention that's kind of what it was. Things were being done, I guess his understanding, that we were unaware of with this blood sample. I guess finding out that we weren't aware of anything or even remembering anything about this.**

Q And at that point you made no effort to reach out to the Department of Health and Human Services about this program; is that correct?

**A No, I did not.**

Q And you made no effort to reach out to any medical professional to ask questions about the program; is that correct?

**A No.**

Q You made no effort to see if your children's dried blood spot cards were even being used at all; correct?

**A Correct.**

MR. KENNEDY: Thank you. Nothing further.

MR. ELLISON: All right. Ashley, I've got a couple follow-up questions for you here, and then we're going to -- you're on your downward slope here, so --

THE WITNESS: Okay.

EXAMINATION

BY MR. ELLISON:

Q For your -- and I'm going to divide this up into two segments, and if you could bear with me.

**A Okay.**

Q As for -- and I'm going to call them Infant by letter, but obviously some of your children are no longer infants anymore, even with the most generous use of the word, but --

**A Yeah.**

Q As for Infant D, my understanding is that Adam is not the biological father of Infant D; correct?

**A Correct.**

Q But you are his biological mother; correct?

**A Yes.**

Q All right. And you have custody of -- legal custody of Infant D as well; correct?

**A Yes.**

Q When Infant D -- when you're going to the hospital -- let me ask it this way. Before going to the hospital for Infant D, did anyone from -- your doctors or anyone from the State of Michigan approach you to explain to you about the newborn screening program?

**A No.**

Q Did anyone present to you information that would balance the risks versus the benefits to participating in the newborn screening program?

**A No.**

MR. LEVIN: I'll note --

MR. ELLISON: I'm sorry?

MR. LEVIN: I'll just note my objection to relevance, but she answered already.

MR. ELLISON: Yeah.

Q As of -- did anyone from the Michigan Neonatal Biobank ever present any information to you explaining the negative -- or the risk or benefits of participating or otherwise continuing with the newborn screening -- or, excuse me -- with storage blood? Let me start over again on that. Too many -- too much word salad there. Before Infant D was born, did anyone from the Michigan Neonatal Biobank present themselves to you or provide information to you that explained the benefits versus the risks of storing newborn blood at the Michigan Biobank?

A **No.**

Q All right. At the time that you were at the hospital, did anyone from the hospital or any agent of the state or representative of the biobank, come to you at the hospital and explain to you the benefits versus the risk of being -- of participating in the Michigan newborn screening program and/or the biobanking system?

A **No, not that I'm aware of.**

Q Again, this is for Infant D. This is your first one. Do you remember signing any form relative to Infant D at all?

A **No.**

Q After Infant D was born, again, same question. Anyone from the state, from the biobank, or your doctors provide any information to you explaining to you the risks versus the benefits of participating in the newborn screening program or the biobank?

A **No.**

Q Did anyone even tell you that they were taking his blood to be sent to the state for testing and for later storage?

A **No, not that I'm aware of.**

Q Okay. As for your other two children, I'm going to go through the same question as to Infant R and Infant C. Again, would your answers be any different about whether someone from the state, the biobank or your doctors, before, during or after their births, came to you and did -- and

explained to you or gave you documentation that said, "Here are the risks. Here are the benefits of participating in the newborn screening program or the biobanking system"?

**A No.**

Q Do you have -- I guess a number of questions have been asked to you today about whether you have any firsthand information about whether or not your children's -- any of your three children's blood spots have been used, sold, or otherwise accessed in any way. Is that your main concern with this lawsuit about whether they're actually being used?

**A Can you repeat that one more time? It cut out a little bit. I'm sorry.**

Q Yeah, no problem. So throughout the questioning today by both Mr. Levin and Mr. Kennedy, they both have been asking you about the concerns you -- if you have any evidence of actually having your children's blood samples accessed or otherwise used. Is that your primary concern about whether or not they've been used to date?

**A Yes.**

Q Does medical privacy have any concern for you for your children?

**A Yeah.**

Q What about medical privacy concerns you about the biobank -- for particularly the biobank system having your children's blood samples on file?

**A Just not knowing what's being done with it or what information is being given anywhere else, I guess. The unknown makes me wonder.**

Q All right. And is that a concern and fear that you have that the lack of information would result in your children's medical privacy and medical data being disclosed to third parties?

**A Yes.**

Q Have you ever given consent to anyone to transfer your children's blood from the State of Michigan to the Michigan Neonatal Biobank?

**A No.**

Q If knowing that -- as you've somewhat probably pieced together here today with the deposition and knowing -- I'm going to make a representation to you that your child's newborn blood, regardless of which selection you pick, is indefinitely stored at the biobank, absent your directive to destroy them. If you knew that at the time, would you have consented to participating in the program?

MR. KENNEDY: Objection; calls for speculation.

Q Go ahead.

**A Probably not, no.**

MR. ELLISON: Exhibit A.

(Counsel shares document via video)

MR. LEVIN: Yes. How's that?

MR. ELLISON: That's perfect. Thank you.

Q Exhibit A, Ashley, has anyone from the State of Michigan, your doctors, or the biobank, ever presented you with this form to give you the option to execute this document?

**A No.**

Q All right. And as I notice --

MR. ELLISON: And if you could scroll down a little bit, Aaron, on there to the very bottom.

Q I notice on the very bottom it says -- just because I'm an attorney and I look for these things, I notice that it says, "Rev.2-19." Does that statement mean anything to you?

**A No.**

Q All right. If I was to tell you that this was a document that was produced and made in 2019, would that document have been available to you at the time your children were born?

**A No.**

MR. ELLISON: You can take that down, Aaron.

Q At any point has anyone from the neonatal biobank ever sought your permission or your confirmation that they would -- they would -- or that you or your husband would like to continue to have the blood spots stored at the Michigan Neonatal Biobank?

**A No.**

Q I'm going to make another representation to you. One of the blood samples is not stored at the neonatal blood bank.

It's actually stored at a separate location called the BioTrust in a warehouse in Lansing, Michigan. Are you aware of that?

**A No.**

Q Has anyone from the State of Michigan indicated to you that a -- one of the blood samples has been taken away from the blood that's been transferred to the biobank and kept for purposes -- for the benefit of you and your husband?

**A No.**

Q Have you ever given permission to the State of Michigan to keep that blood sample to your knowledge?

**A No.**

Q Do you feel that as a mother of your three children, that the decision about what your children's -- who has access to your children's medical DNA and biological samples should be a decision you should have, and they should obtain your consent before their use?

**A Yes.**

MR. KENNEDY: Objection; calls for a legal conclusion.

Q I'm sorry, Ashley. Go ahead.

**A Yes.**

Q Do you feel that you were adequately informed about the nature and the scope of the newborn screening program, including indefinite retention of that sample at the

Michigan Neonatal Biobank, at the time or shortly after your children were born?

**A No.**

Q Does it make you concerned, angry, upset or any other feelings that you found out about this after the fact?

**A Concerned.**

Q Okay. I know you've mentioned earlier you talked to your husband, and your husband is an attorney; correct?

**A Yes.**

Q All right. Is he your attorney?

**A Yes.**

Q I mean, obviously outside of the newborn blood screening lawsuit where I'm your attorney, would you consider him your general attorney for purposes of legal advise?

**A Yes.**

Q My wife does, too. I'm not good with taking out the trash, but apparently I'm good with legal advise, so there you go.

**A There you go.**

MR. ELLISON: Ashley, I have no further questions. I appreciate your time today. We reserve the balance of our questions for trial. Thank you.

THE WITNESS: Thank you.

MR. ELLISON: The other two gentleman might have some follow-ups.

THE WITNESS: Okay.

MR. LEVIN: Yeah, just a moment.

EXAMINATION

BY MR. LEVIN:

Q You indicated during your testimony that you're concerned about the unknown as it relates to these programs?

**A Yes.**

Q Did you ever do any independent research to find out more about the programs?

**A No.**

MR. LEVIN: I don't have anything else.

EXAMINATION

BY MR. KENNEDY:

Q Ms. Kanuszewski, your attorney asked you if anybody ever notified you about the benefits and risks of participating in either the newborn screening program or the biobanking system. What, in your mind, are the risks of participating in the newborn screening program?

MR. ELLISON: Objection; calls for a medical opinion and, perhaps, a legal opinion from a lay witness. Ashley, go ahead and answer if you can.

**A Just like Phil said, the medical -- what they're using it for. Are they giving information on my, you know, DNA -- my children's DNA to other people or just not knowing where this is going or what it's being used for.**

Q Do you have any evidence of anybody using your children's

DNA for anything?

**A No.**

Q So this is a speculative risk, not an actual -- not an actual concern that you've seen happen already?

MR. ELLISON: Objection; calls for a legal conclusion but go ahead.

**A Yes.**

Q Do you have any evidence of anyone's genetic information being obtained from the newborn screening program?

**A No.**

Q And what are the risks to you, in your opinion, of participating in the biobanking system?

**A To me? I don't know.**

Q In your opinion, what are the risks of participating in the biobank?

**A I'm not sure. I guess I don't know. I'd want to know what the risks are if there are any.**

Q So you don't even know if there are any risks. Is that what you're just testifying to?

**A Yeah. But I would like to know. I feel like there could be. I don't like not knowing where or what they're using it for.**

Q And because of those concerns, you took precisely zero action, prior to filing this litigation, to investigate; is that correct?

**A True.**

Q So how serious are those concerns then if you are -- didn't take any action whatsoever to look into them?

**A I've mostly left it to my husband.**

Q Okay.

MR. KENNEDY: Thank you, nothing further.

MR. LEVIN: I have a follow-up, although you can go first. I should have asked a moment ago. I just want to make everyone aware.

MR. ELLISON: That's fine. We can keep going. I have one more follow-up as well, but either way. Aaron, if you want me to go or you want to go, it's up to you.

MR. LEVIN: I'll jump in. I should have asked a minute ago, and then you can address everything at the end.

EXAMINATION

BY MR. LEVIN:

Q You testified that you don't remember before, during, or after the birth of your children that anybody gave you any information about these programs. Do you remember for certain that no one gave you that information, or do you not recall being given that information?

**A I don't recall being given any information.**

MR. LEVIN: Okay. Thank you. That's all.

EXAMINATION

BY MR. ELLISON:

Q Ashley, as part of your -- when you first learned of the newborn screening program and the biobanking system from your husband, had he discussed with you about hiring me to represent your interests as to the scope of what's going on with the biobanking system?

**A Yes.**

Q And you, in fact, did hire me to pursue legal action and to represent you and your children's interest as it applies to the biobanking system; correct?

**A Yes.**

Q And that would have been work that I would have done for you before filing the lawsuit; correct?

**A Yes.**

MR. ELLISON: Thank you very much. Anybody else?

MR. LEVIN: That's all I have.

MR. KENNEDY: No.

(Deposition concluded at 4:19 p.m.)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 26

## Deposition of Shannon LaPorte

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v Case No. 18-cv-10472

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, HON. THOMAS L. LUDINGTON
MAG. PATRICIA T. MORRIS

Defendants.

/

VIDEO CONFERENCE DEPOSITION OF SHANNON LaPORTE

Taken by the Defendant MDHHS on the 23rd day of October, 2020, via Zoom, at 11:00 a.m.

APPEARANCES:

| | |
|---|---|
| For the Plaintiffs: | MR. PHILIP LEE ELLISON (P74117)<br>Outside Legal Counsel PLC<br>PO Box 107<br>Hemlock, Michigan 48626<br>(989) 642-0055 |
| For the Defendant MDHHS: | MR. AARON WARREN LEVIN (P81310)<br>Michigan Department of Attorney General<br>PO Box 30736<br>525 Ottawa Street<br>Lansing, Michigan 48909<br>(517) 335-7632 |
| For the Defendant Michigan Neonatal BioBank and Antonio Yancey: | MR. JEREMY C. KENNEDY (P64821)<br>Pear Sperling Eggan & Daniels PC<br>24 Frank Lloyd Wright Drive, Suite D2000<br>Domino's Farms<br>Ann Arbor, Michigan 48105<br>(734) 665-4441 |

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Via Zoom Video Conference

Friday, October 23, 2020 - 10:59 a.m.

MR. LEVIN: All right. Thank you. I'll just dive right in. I don't know if you've ever done a deposition before, have you?

MS. LaPORTE: No.

MR. LEVIN: All right. So we're here for a deposition. I have just not too bad a list of questions here for you. I'll run through those. It's being recorded, so we need to both do our best not to talk over each other because then the transcript isn't clear and everybody gets mad at us. Yeah, so I'm going to just run through some questions, and then Mr. Kennedy and Mr. Ellison may also have some questions for you. It should be pretty straightforward.

If you don't know, feel free to say you don't know. That's a perfectly acceptable answer. If you don't understand, let us know. Let me know. If you don't remember, also a perfectly acceptable answer. That is all right. And then the last thing is you might hear, depending on who's asking the questions, somebody else object. For the most part, after the objection, you'll still answer, and then we will hash that out later between us. If it's one where you won't answer, I'm sure we will all jump in and tell you not to answer.

MS. LaPORTE: Okay.

MR. LEVIN: All right. I am going -- any other preliminary matters from anybody?

MR. ELLISON: No. I mean, let me -- I would say -- I would say is is that I assume we're all stipulating to do this by Zoom. I know some of the court reporters have required it, consent. To the extent a consent is required, we have no objection and consent to doing a Zoom deposition.

MR. LEVIN: I appreciate that. Thank you.

MR. ELLISON: Yup.

MR. LEVIN: All right. So I will dive right in.

REPORTER: Do you solemnly swear or affirm that the testimony you're about to give shall be the whole truth?

MS. LaPORTE: I swear.

SHANNON LaPORTE

having been called by the Defendant MDHHS and sworn:

EXAMINATION

BY MR. LEVIN:

Q So this a lawsuit regarding the Michigan Department of Health and Human Services retention of blood spots. So I'm just going to start with what concerns do you have about the Department of Health and Human Services retaining residual dried blood spots?

**A All of the concerns? What right do they have to take and store mine and my kids' DNA without us having given**

**permission. What they're going to do with it. What if somebody broke in and took all of that information that I'd never given permission to have. There's a lot of concerns, laundry list.**

Q Anything else specifically?

**A Not that I can think of other than what I've listed.**

Q What would you like to see happen to your children's blood spots at the conclusion of this lawsuit?

**A I'd like them destroyed.**

Q Are you aware that you can direct the Department of Health and Human Services to destroy the blood spots at any time?

**A Nope.**

Q You're not aware of that?

**A No.**

Q All right. I am going to attempt to share my screen here for just a moment. Bear with me. I am not going to share my screen. I do not have that ability.

**A Describe it.**

MR. ELLISON: I think Pam can give you permission by making you, like, a co-host or a host.

REPORTER: Yeah. Usually I just have a button here I can click, but it's not -- it's not letting me do it.

THE WITNESS: I can share my screen.

MR. LEVIN: So I just have a one-page Word document. If I email that to you, is that something you can

share?

REPORTER: Me?

MR. LEVIN: Yes.

REPORTER: Yes.

MR. LEVIN: All right. Where should I send that?

(Off the record)

(Reporter shares document via video)

Q All right. Before we went off the record, I was asking if you are aware that you have the ability to have your children's blood spots destroyed at any time, and you indicated you did not. So I'm going to direct you now to --

MR. LEVIN: I guess we'll mark this as Exhibit A, and it's the residual newborn screening blood spot directive.

(Deposition Exhibit A marked)

Q Have you ever seen this form before?

**A No.**

MR. ELLISON: Shannon, your internet left there.

THE WITNESS: No. Oh, sorry.

**A No, I have not seen this one before.**

Q All right. If you would just take a moment and review it and let me know. No rush, but let me know when you've had a chance to look it over.

(Witness reviews exhibit)

**A Okay. I've reviewed it.**

Q Would you agree this form allows you to have your children's blood spots destroyed?

MR. ELLISON: Objection. Calls for a legal conclusion. Go ahead and answer, Shannon.

**A Could you repeat the question?**

Q Sure. So noting the objection, would you agree that reviewing that -- after reviewing this form, it allows you to have the department destroy your children's blood spots?

**A I don't agree with this form, so I'm going to say no.**

Q Why don't you agree with it?

**A Because this shouldn't even exist.**

Q But it -- strike that. I'll rephrase.

**A Having not seen this form, and already having gone through a situation where my children's DNA and blood spots were taken, I do not agree with this form.**

Q So I understand you don't think the form is necessary. Does the form purport to allow you to have the blood destroyed?

MR. ELLISON: Same objection, same objection.

MR. LEVIN: Fair enough.

**A Can I say "same answer"?**

MR. ELLISON: Just answer the question as best you can as Mr. Levin has put it to you.

**A Having never seen this form before --**

Q Would you like more time to --

**A I didn't know it exists. I didn't know it existed, so it**

**didn't do me any good until this point. And if it didn't exist when the blood spots were taken, what good does that do me? So now it's my burden to make sure that something I didn't know happened can be destroyed. So I'm going to go with "no."**

Q So your position is that, no, this form does not allow you to have blood spots destroyed?

MR. ELLISON: Same objection.

**A I don't know it exists.**

MR. LEVIN: So that was same objection from Mr. Ellison.

Q And just to clarify the record, if you could just repeat your answer.

**A I didn't know it existed. This form isn't relevant since this information wasn't provided to me.**

Q It's been provided to you now, though. So I'm going to just -- I'll approach this a little bit differently. Do you see a little bit down it says, "I am a legal representative"?

**A I do.**

Q Do you see the first box under that?

**A I do.**

Q Could you read that sentence for me?

**A "Signature of parent, guardian, or other legal representatives."**

Q Sorry. The little chat box above that.

**A "Store but not use blood spots" -- sorry. I'll repeat myself.**

**"Store but not use blood spots for research after newborn screening is complete. I understand that the blood spots will be kept by the laboratory but not used for research of any kind unless directed in writing by me."**

Q All right. So if you could go two above that. It starts, "Destroy all remaining blood spots."

**A Okay.**

**"Destroy all remaining blood spots. I understand that by checking this box, no blood spots will be available for any future use including medical, identification, or research purposes."**

Q Going forward, is that what you're seeking?

**A Yes.**

MR. LEVIN: All right. That's all I need from this form, so I think we can end the screen sharing at this point. Thank you.

REPORTER: Mr. Levin, it looks like you can screen share now just in case you need to.

MR. LEVIN: I can. Thank you. All right. And actually, I am going, I think, to do that. If this will -- let's see how this looks.

(Counsel shares document via video)

MR. LEVIN: Can you all see that?

MR. ELLISON: Yes.

MR. KENNEDY: Uh-huh (affirmative).

Q Do you recognize this form?

**A No. What's the date on that? 2/6 -- what? '17, oh, my goodness. No.**

Q Do you -- strike that. Let me start over.

MR. ELLISON: I'm going to step off screen for just a moment, but I can still hear everything that's going on. So just go ahead and continue.

MR. LEVIN: Okay. Thank you.

(Off the record interruption)

**A Sorry. I have children.**

Q That is all right. That is all right. All right. I'm going to direct you, I think first, to the signature on this form. Does that appear to be your signature?

**A It does.**

Q Do you recall ever seeing this form before?

**A The day I saw the form I was knocked out for a period of time.**

Q Would you agree that the, "No, my baby's blood spots may not be used for health research" box is checked?

**A Yeah. And that goes right along with how I feel about it, so I mean, that makes sense. I just have no recollection of**

**it.**

Q So if your baby's blood spots are not being used for health research, is that consistent with what you just said you wanted?

**A Yes.**

MR. ELLISON: And, Aaron, can we agree that's Exhibit 2?

MR. LEVIN: I think I used A, so maybe it should be B.

MR. ELLISON: B. Okay. Very good.

MR. LEVIN: Yes. I will email this around as well. I can do that -- at the end of the day I can send all of them, or I can send this one in just a few minutes.

MR. ELLISON: No, that's fine. End of the day is fine, just as long as we're clear. And then if you could put, you know, something on it that just shows that was B. Just put a stamp or a -- you know, even a tech stamp, whatever, just that we're clear when we get the email from you.

MR. LEVIN: Yeah. I can do that ahead of time or before I email it around or --

MR. ELLISON: Yeah. Don't do it right now. Just do it after the deposition is fine.

MR. LEVIN: Great. Of course.

THE WITNESS: This is way better than a court

room.

MR. LEVIN: Well, I'm glad we could at least accommodate that.

(Deposition Exhibit B marked)

Q Do you recall if you were ever given an educational pamphlet or brochure regarding the newborn screening program?

**A No, I don't believe I was. I do not recall receiving one or going over one or reading one. I mean, I remember a lot of things from the hospital. Safe sleep, I could tell you the whole spiel. I have no recollection of newborn screening.**

Q Do you recall if you were ever given an educational pamphlet or brochure explaining that residual blood spots may be retained and used for medical research?

**A No.**

Q Do you know or recall if you have any files related to that in your possession?

**A I don't.**

MR. LEVIN: I think that is all I have. So I will -- Jeremy or Phil, I don't know if there is a preferred order. I don't know if you have anything.

MR. KENNEDY: I have some questions. Phil, if you don't mind?

MR. ELLISON: Go ahead, fantastic.

MR. KENNEDY: All right. Thank you. Good morning, Ms. LaPorte. My name is Jeremy Kennedy. I'm the

attorney for Dr. Antonio Yancey from the Michigan Neonatal Biobank. I just have a few questions for you.

EXAMINATION

BY MR. KENNEDY:

Q So if you look at Exhibit B from -- Mr. Levin provided, it said you did not consent to using the blood spots for testing; correct?

**A Correct.**

Q Do you have any evidence, information, or documentation that would indicate that your baby's blood spot cards are being used for testing or research?

**A Do I have any documentation stating otherwise than what that document says? Is that what you're asking me?**

Q I'm asking if you have -- if you have anything that would lead you to believe that the blood spot cards for your child are being used other than -- are being used for research contrary to what you requested?

**A I don't know.**

Q You don't know?

**A Don't know.**

Q But you don't have any evidence of that?

**A No, not that I know of.**

Q Okay. Do you have any evidence that the biobank is -- has, in any way, profited from your child's blood spot cards?

**A No, I don't.**

Q Okay. And you indicate that there is no use of the blood spot cards that you would find acceptable; is that correct?

**A Correct.**

Q And until today, you were unaware that you could request the destruction of the cards; correct?

**A Correct.**

Q Now, the signature on Exhibit B, you testified that is your signature; correct?

**A That is my signature.**

Q And you don't recall signing that document?

**A Zero recollection of that.**

Q And it looks like it was signed the date your child was born; is that correct?

**A That is correct.**

Q The birth of the child, was that natural delivery or C-section?

**A C-section.**

Q C-section? Did they put you out entirely, or did they give you an epidural?

**A I don't get -- so it's more -- it's a direct tap. It's not an epidural, because those don't work for me. I don't know if it's spinal tap or -- not spinal tap, but I can't remember the exact definition of what it's called. But it numbs the entire -- and it lasts for like 18 hours or something.**

Q Okay. Were you ever unconscious?

**A Yes, for about two hours.**

Q Okay. And for how long?

**A About two hours.**

Q Okay. And was that a result of whatever medication they had to give you for the C-section?

**A It was from the C-section and pain on top of -- so shortly thereafter, after delivery.**

Q Okay. And obviously I've never given birth, but my wife just went through that less than two weeks ago and --

**A Oh, yeah.**

Q And I can understand it's a painful process. So I do sympathize. But you don't recall if you signed that document before the delivery, after the delivery or --

**A I have no idea.**

Q Okay.

**A Part of the delivery was fairly quick, so I mean -- I don't think I signed -- really just the consent to deliver. I mean, I don't think there was anything other than that in my paperwork. For that one I went into labor, and I had a scheduled C-section, so they had to go a little quicker because I was already in active labor.**

Q So was it an emergency section?

**A It wasn't considered an emergency scenario, but it was not a standard procedure just because I was in active labor.**

Q Sure. Okay. And just going back to what you -- one of your concerns was the access to the DNA of your children. Do you have any information that would indicate that their -- any of their genetic information has been accessed?

**A I don't.**

Q Okay. And do you have any -- do you have any personal knowledge of how the Michigan Neonatal Biobank operates?

**A I don't.**

Q You have no information about how it's funded; is that correct?

**A Correct.**

Q And no information about any of its policies regarding the dried blood spot cards; correct?

**A Correct.**

MR. KENNEDY: Thank you. I have nothing further.

MR. ELLISON: Shannon, I have a couple of questions for you for the record. And just for purposes today, I, of course know the name of your children. But because of federal court rules, we have to refer to them by initials. Okay?

THE WITNESS: Okay.

EXAMINATION

BY MR. ELLISON:

Q The case here involves -- I'm going to call it "Infant M" which is your child that was born in 2008.

A **Okay.**

Q And also Infant E which was the one born in 2017. Okay? And I don't mean any disrespect by that or to minimize it. It's just that's the way we have to do it for these types of things. Okay?

A **That's fine.**

Q Today you've been asked about, and you were presented with a copy of the document, Exhibit B, which was a card that contains your signature. And that one involves baby -- or Infant E; correct?

A **Correct.**

Q Has anyone showed you any consent card or any information today about Infant M?

A **No.**

Q Did you at any time -- I want to go through both those children separately right now with you. As for Infant M, did anyone from the State of Michigan ever come up to you and explain about the newborn screening process before Baby M was born?

A **No.**

Q Did anyone provide you with the benefits and risks that are involved with participating in or otherwise consenting to a process that would involve the pricking of your child's foot and taking the blood sample for testing?

A **No.**

Q Did anyone from the State of Michigan or a state agent in any way, whether it's the doctor or anybody else, go through and explain the process by which the blood would be drawn from your child's body?

MR. LEVIN: I'm going to object just to relevance. That's been stricken, but --

Q Go ahead.

**A No.**

Q Okay. After the blood -- I'm going to ask you to assume that the blood was drawn from your child's body and placed on what are called blood spots on the Guthrie card. A Guthrie card, just so we're clear for both sides, is a device that's used to collect the blood spots on a paper -- on a type of paper. Okay? After the blood spots were extracted, did anyone from the State of Michigan or agent, being a doctor or anybody else, explain to you what the scope of the uses of those blood spots were going to be for Infant M?

**A No.**

Q Did anyone ever tell you or explain to you that what would happen to those blood spots after those blood spots were -- the testing on those were completed?

**A No.**

Q Did anyone ever explain to you what the Michigan Neonatal Biobank was as to Infant M?

**A No.**

Q Okay. Did anyone ever explain to you about the scope of the potential uses of your child's -- of Baby M -- or Infant M's blood spots while they were being stored in the newborn -- or in the Michigan Neonatal Biobank?

**A No.**

Q Do you have any concerns about your child's medical privacy right now assuming those blood spots are in the Michigan Neonatal Biobank?

**A Yes.**

Q What are your medical privacy concerns for Infant M?

**A Well, I don't know the policies regarding who is holding on to those samples. I don't know what they have plans to do with them. I don't know what they can do with them. I don't know what rights we have as -- when you don't know someone has something of yours, it's kind of hard to know where you stand with rights. So now that -- you know, I don't have a clue what -- I just feel like we've been violated completed. Why is a piece of our DNA being stored in a bank? For what purpose?**

Q Would you object to the State of Michigan using your child's DNA without your consent or knowledge?

**A Yes, I would object.**

Q And would you -- same objection for the Michigan Neonatal Biobank?

**A I would object to anybody using our DNA or blood spots for research without permission.**

Q Okay. And I'm not talking just research. I'm talking for any purpose that you --

**A For any purpose. For any purpose. For any purpose whatsoever. There is no purpose for my blood or my children's blood to be used for anything.**

Q Okay. Were you ever provided the option to opt out or otherwise decide you did not want to participate in either the newborn medical screening or the storage of those blood spots with the Michigan Neonatal Biobank before the blood was extracted?

**A Not that I know of.**

Q Okay. Were you given that option after the blood was extracted?

**A No.**

MR. ELLISON: Aaron, can you put up Exhibit Number B on the screen?

MR. LEVIN: Yeah.

(Counsel shares document via video)

THE WITNESS: Number B? Is that what --

MR. ELLISON: Yeah, letter B.

REPORTER: And, I'm sorry. What was your answer to that last question?

MR. ELLISON: Could you read back the question?

(Playback of previous question)

**A No, not that I know of.**

Q Shannon, on your screen right now is a -- what has been marked as Exhibit B for purposes of this deposition. And this is the card that involves Infant E; correct?

**A Correct.**

Q And this would be your child that was born on February 6, 2017?

**A Correct.**

Q Okay. Looking at this card right here -- and I know --

MR. ELLISON: And maybe, Aaron, you can zoom -- if you could zoom in a little bit so we could see the "X" a little bit better?

MR. LEVIN: Is that too much?

MR. ELLISON: There you go. That's a little better.

Q You've had time to review this Shannon, and can you tell me if there is an option provided to you as a parent -- assuming this is the card that was presented to you -- that would allow you to completely opt out of any storage of any newborn -- of your newborn's blood?

**A No.**

MR. LEVIN: I can zoom in more if you need it.

Q I'm looking in the box that's checked "no," the first bullet point right below that does go on to say that --

**A Oh, yeah. "I must contact DHS if I do not want" -- "if I do not want blood spots stored for any reason after newborn screening." I do see that on there.**

Q All right. And in that right there is -- is that -- it does say that blood spots will be stored forever but not used for research. Were you provided with any information about what those blood spots would be used for, even though the fact that you're saying "you don't want them to be used for research"?

**A Repeat that again, please.**

Q Fair enough. What I'm trying to understand here is I'm looking at these options, and one of the options that is not available to you is to opt out of the whole process altogether; correct?

**A Correct.**

Q All right. And this would be before any sort of blood spots were being taken for any part of this program; correct?

**A I have no idea when they presented this card to me.**

MR. ELLISON: All right. Aaron, I'm done with that screen right there.

Q Same questions I want to go through real quickly, Shannon, for Infant E. Before you were -- before Infant E was born, were you ever made contact or presented by an agent of the state that explained the positives and the benefits and the risks or potential harms of participating in the newborn

screening program?

**A No.**

Q And I believe you testified earlier that you weren't provided with any sort of pamphlet; correct?

**A No. Not that I -- I have no pamphlet. I have no pamphlet in any of my paperwork.**

Q Okay. And you did look at my request; correct?

**A Yeah.**

Q All right. When the newborn -- at the time that you were in the hospital and the baby was born, did anyone come to the hospital and explain to you that they were going to be extracting the blood spots from your child's foot for medical testing and/or storage of the newborn -- or, excuse me -- the Michigan Neonatal Biobank?

**A No.**

Q Same question but as to the time frame being after your child was born?

**A Not -- no. I was in the hospital for four days, and I have no recollection of that at all.**

Q If you had known that the program would have included turning over your child's blood spots for research -- whether it was for research or not, to the Michigan Neonatal Biobank, would you have consented to that process? I'm sorry?

**A No.**

Q And that's true then? That would be true then?

**A Yes; yes. That would have been true always.**

Q And that would be true today?

**A Correct.**

Q Has anyone from the Michigan Neonatal Biobank sought permission or consent from you to store your child's blood within their custody or control?

**A Not that I know of.**

Q Okay. Has Dr. Yancey or an agent of Dr. Yancey's ever contacted you about storing your child's blood with your consent at the Michigan Neonatal Biobank?

**A Nope. Don't know who Dr. Yancey is.**

Q Has any paperwork that you've seen today or previously ever even included the Michigan Neonatal Biobank?

**A Not that I recall. Never heard of it before.**

Q Do you know of the relationship and the scope of responsibilities between the State of Michigan and the Michigan Neonatal Biobank?

**A No.**

Q As it stands today, do you know of any legal protections or limitations on the use of your child's blood in the neonatal biobank being under the custody and control of Dr. Yancey?

**A No.**

Q Does that concern you?

**A Yes.**

Q And why does it concern you?

**A Because why does someone else have full control of my -- not only mine, but my children's DNA and blood spots? For what? That doesn't know -- there's so many reasons why it concerns me, I can't -- there's so many reasons.**

Q And if I -- I guess to cap out here, would your -- I mean, obviously you've been presented today with Exhibit A, which would allow -- a document that would allow for you to destroy those blood spots going forward. However, is it your position today that your child's blood spots should have never been in the position that they are today, and you don't even need the use of that form?

**A Exactly. That is my exact position.**

Q And do you feel that, to the extent that this violates your rights in any way, you would like me to be -- as your attorney, to be able to rectify and remedy those wrongs; correct?

**A Correct.**

MR. ELLISON: I ave no further questions.

MR. LEVIN: I have a few just briefly.

EXAMINATION

BY MR. LEVIN:

Q So you testified that around the time of the birth of any of your children, nobody informed you about the newborn screening program or any of the related research uses. Do

you remember that that did not happen, or do you not recall that it may have happened? Does that make --

A **I have no memory of any of that happening. They give you a lot of information when you go to have a human. They give you a lot, a lot, and there's a lot of things happening during that time. So I have no -- I could not tell you --**

THE WITNESS: -- as my internet -- can you hear me?

MR. ELLISON: Yeah.

MR. LEVIN: Yeah, we can hear you now.

A **I have no memory of any newborn screening program. I have memory of safe sleep and safe feeding habits and how to make them latch. I have nothing for you on a newborn screening program. I have no recollection of that, and I have three children.**

MR. LEVIN: I think that's all I have.

MR. KENNEDY: Just a couple brief questions.

EXAMINATION

BY MR. KENNEDY:

Q Ms. LaPorte, when did you -- you've testified you don't recall anything from when you were in the hospital with any of your children about the dried -- the heel prick and the dried blood spot cards. When did you first find out about the dried blood spot cards and that your children had blood spots being stored?

**A I think it was a random -- you know, I don't really know.**

Q Okay. Do you recall where you -- how you heard about this?

**A I don't.**

Q Did you ever contact anybody to find out more information about the program?

**A I mentioned something to one of my doctors, but she didn't really seem to know much either. And that's -- it just kind of ended there.**

Q Never contacted anybody from the State of Michigan Department of Health and Human Services?

**A No.**

Q Never did any research to see what the biobank was?

**A I didn't know it was a biobank.**

Q You hadn't heard of them -- when did you first hear about the biobank?

**A During this process.**

Q Okay. And you didn't know what the state could do with the dried blood spot cards?

**A I still don't.**

Q Have you ever done any research to find that out?

**A I mean, it's very limited what I can find unless I know somebody that works there that knows the things. Because that stuff is not just posted. I mean, there's very little information available online.**

Q And it's your testimony that if Exhibit A, the form that was

provided, allows you to have the dried blood spot card destroyed, you're not willing to sign that form? Did I understand that correctly?

**A I didn't say that.**

Q Okay. Well, then if the form that was provided as Exhibit A allows you to have the dried blood spot cards for you and/or your children destroyed, would you?

**A I would.**

Q Okay. And this is the first time you've heard of that form today?

**A Today, yes.**

Q Did you ever make any requests to see if there was a way, short of filing a lawsuit, you could have the dried blood spot cards destroyed?

**A No. I shouldn't have to go through that. I shouldn't have to go through that work. Why is that my burden? Why -- why when -- I'm in such a state -- I mean, there's a lot of times when it would be a good time to inquire about whether or not someone could take my newborn's blood sample. During the frills of delivery and birth is not the best time.**

Q You're misunderstanding the question. I'm not asking about when the baby is being born. I mean at any point after that.

**A I don't think I should have to -- that burden shouldn't be placed on me. The option should be given to me the moment**

**that -- option for it to happen, happens to begin with.**

Q Do you object to the state testing your child to see if they have any sort of -- any of the conditions that could be detected through the newborn screening process?

**A Okay. But -- no. I don't have any objections to the testing. I have objections to the storing. There should be no storing or testing for diseases and things. And we know if we have it; we don't, we don't. Then (inaudible) sample. That's it.**

Q Now, you understand that these tests have to be calibrated; correct?

MR. ELLISON: Objection; lack of foundation.

Q Are you aware that these --

**A I don't understand the question. You can say -- you say "calibrated," but that could be used in a variety of different scenarios and mean different things.**

Q You're aware that these tests have -- are you aware that these tests have to be able to be replicated?

**A No.**

Q You're not?

**A How many times replicated? Where is that? Where is that in my information that I'm receiving?**

Q Are you aware that they have to make sure -- that when the state and hospitals do the screening test, they have to make sure that the tests that they're performing are still

accurate?

**A That seems like a back-ended question. Could you repeat that?**

Q If you are screening for various genetic diseases, chronic conditions --

**A Okay.**

Q -- you have to make sure that those tests that they're performing are accurate; correct?

**A So under that assumption, they get to keep the sample and retest it over and over and over and over again?**

Q You have to keep these -- you want to make sure these tests are accurate; correct?

**A Yeah, I would want the tests to be accurate.**

Q Good. So in order to make sure the tests are accurate, you'd have to be able to calibrate those tests from time to time. Would that be correct?

MR. ELLISON: Objection; lack of foundation.

Q You have to make sure the tests are, in fact, still accurate?

MR. ELLISON: Same objection.

**A I would want the tests to be accurate, but by means -- the means in which they are doing so, I don't believe is accurate. I believe there is a different way.**

Q What would that way be?

**A I'm not a scientist, sir.**

Q Well, you just said there's a different way.

**A I believe there is a different way. I don't believe storing our blood samples forever and always to calibrate your test is the way to do it without out knowledge of you doing it.**

Q But you have no information that your -- that any -- either your or your children's blood spots are being used in any way contrary to what the paperwork you signed says; correct?

**A Correct. Now I'm concerned about how they're being used for re-calibration.**

MR. KENNEDY: Thank you. I have nothing further.

MR. ELLISON: If I may ask just one more question.

EXAMINATION

BY MR. ELLISON:

Q Shannon, what do you do for a living?

**A I work in marketing and merchandising for various companies to better their products, and I write reviews and speak with a lot of different people.**

Q You're not a medical scientist or a medical researcher?

**A (No verbal response)**

Q I'm sorry?

**A No, unfortunately; no.**

Q Do you have any degrees in science or biology or genetics in any way?

**A No.**

MR. ELLISON: Thank you very much? Unless there's

any other questions?

MR. LEVIN: No, that's all I have.

MR. ELLISON: All right. Very good. Shannon, thank you so much today.

(Deposition concluded at 11:46 a.m.)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 27

## Deposition of Lynette Wiegand

STATE OF MICHIGAN

EASTERN DISTRICT OF MICHIGAN

NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v File No. 18-cv-10472

HON. THOMAS L. LUDINGTON
MAG. JUDGE PATRICIA T. MORRIS

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,

Defendants.

/

# DEPOSITION OF LYNETTE WIEGAND

Taken by the Defendants on the 7th day of January, 2021, via Zoom, 10:00 a.m.

APPEARANCES:

| | |
|---|---|
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EXHIBIT INDEX

Via Zoom

Thursday, January 7, 2021 - 10:03 a.m.

(Deposition Exhibits A through E marked)

MR. LEVIN: Good morning. My name is Aaron Levin. I am the attorney representing the group of Defendants that work for the Department of Health and Human Services, so that's Director Gordon -- Director Robert Gordon, Dr. Sandip Shah, Dr. Sarah Lyon-Callo and Mary Kleyn. I think that's the group.

So I don't know if you've attended or been a part of a deposition before, just there's a couple things I'll run through real quick and then we'll get going. We're being recorded, that means just a couple of things. One, we will all do our best not to talk over each other, that will keep the transcript clear and everybody happy. It means we need to just all try to use "yes" and "no" instead of "uh-huh" and "unh-unh," because those don't come up in writing very clearly. And we'll jump in and mention that if any of start doing that. And what other preliminary things? Oh, yeah, so I think the three of us are going to ask you questions. You may hear somebody object, in general after an objection you'll still answer the question but we'll let you know as that arises. If anything else comes up we will let you know, preliminarily that's all that's coming to my head right now. So -- I think I'm forgetting one thing, but

we'll get it when it comes up. So with -- oh, if a question doesn't make sense, feel free to let us know, ask us to rephrase. If you don't know the answer that is perfectly acceptable, you can just answer "I don't know" and we can either ask it again or just move on. That may have been the thing I was forgetting. So now we will jump in.

REPORTER: Do you solemnly swear or affirm the testimony you're about to give will be the whole truth?

MS. WIEGAND: Yes.

LYNETTE WIEGAND

having been called by the Defendant Michigan Department of Health and Human Services and sworn:

EXAMINATION

BY MR. LEVIN:

Q So you are the Plaintiff in a lawsuit that was filed regarding the Michigan newborn screening program. So my first question is when did you first find out about the newborn screening program?

**A That would have been mentioned -- I don't know exactly which appointment.**

Q An appointment for what?

**A I'm -- at the hospital is when -- well, I know newborn screening was at the hospital because that was the 24 hour screening.**

Q So it was at the hospital around the time -- or what were

you at the hospital for? Let me ask it that way.

**A Delivery.**

Q Was this before delivery, if you remember?

**A No.**

Q So it was after delivery?

**A Yes.**

Q Do you remember how you -- so it was at the hospital, do you remember specifically how you were informed?

**A It was when they came to do the foot prick that they said that -- yes, at the hospital when they came to do the foot prick they said they were doing the 24 hour newborn screening that everybody has done.**

Q So it was hospital staff that informed you?

**A Yes.**

Q Do you recall how you found out about what I'm referring to, just for this conversation as the biotrust program? So let me rephrase. Are you familiar with the term "the biotrust program"?

**A No.**

Q Are you familiar with the Department of Health and Human Services program that allows for the storage and possible use for research purposes of retained dried blood spots following newborn screening?

**A No.**

Q Are you aware that the Department of Health and Human

Services retains blood spots following newborn screening?

**A After everything was mentioned that's when I became aware of it; after the lawsuit was brought up, that's when I became aware of it. But I was not aware of it before this.**

Q So prior to filing the lawsuit, were you aware that the State retains blood spots?

**A No.**

Q So you only became aware of what I'm calling the biotrust program, that blood spots may be used for medical research, after filing this lawsuit?

**A Yes.**

Q So how did you find out about that portion of -- let me rephrase. How did you find out that blood spots are retained after newborn screening?

**A That I don't remember; I don't remember.**

Q Fair enough. So after learning about the newborn screening program and prior to filing this lawsuit, did you do any independent research about the newborn screening program?

**A No.**

Q You didn't look around online or anything?

**A Not -- not -- no. I've been a little busy.**

Q Did you ever contact the Department of Health and Human Services?

**A No.**

Q And I guess I should say specifically contact them regarding

this program.

**A No.**

Q Have you done any of that after filing the lawsuit? I say "any of that," any research after filing the lawsuit?

**A No.**

Q So I guess I'll ask this this way: If you were not aware that the State retained blood spots prior to filing this lawsuit, why did you file this lawsuit?

**A Because I should know -- like, I should have the right to know or have the option of having my child's blood stored, because if -- like for me personally I wouldn't want it stored.**

Q So I guess let me ask this a little bit differently because that isn't exactly what I'm asking. You said earlier you were not aware that spots were stored until after you filed the lawsuit. So at the time of filing the lawsuit was your concern only the heel prick test?

**A No.**

Q What other concerns did you have at the time of filing?

**A It's just any blood that's taken should not be stored without any information being --**

Q So I understand that issue as we sit here today, but you indicated that in -- I think it was approximately February 2018, when the lawsuit was filed, you were not aware that blood spots were stored. So my question is what was the

problem at that time? To the best of your memory.

**A What was the problem with it being stored?**

Q Well, you've said you didn't know at the time that it was stored.

**A Right.**

Q So what was the basis for the lawsuit if you were unaware that blood spots were stored at that time?

**A I should have been aware of it.**

Q So are you telling me that you filed a lawsuit that you should have known something that at the time you filed the lawsuit you did not know?

**A (No verbal response)**

Q Did that make sense? I think we've lost each other a little bit here.

MR. ELLISON: Do you mind if I add some clarity here, Aaron, because I think --

MR. LEVIN: Sure.

MR. ELLISON: Lynette, when he's talking about filing the lawsuit he's talking about when I physically filed the lawsuit. Right?

THE WITNESS: Okay.

MR. ELLISON: Do you recall there was conversation we had prior to filing the lawsuit about the newborn screening program?

THE WITNESS: Right.

MR. ELLISON: What he's asking about is is that he's trying to learn when did you come about and learn about the newborn screening program and the biotrust program, and he's talking about the date of filing was after you and I spoke and we talked about this; correct?

THE WITNESS: Yes.

MR. ELLISON: And I guess what he's trying to understand -- he's using the date of filing as the line of demarcation right now; right? And his question earlier was did you know about the program before I physically filed the lawsuit on your behalf.

THE WITNESS: Oh. Okay.

MR. ELLISON: Okay? I can see the confusion here on my end. Okay? So to be clear, what he's trying to -- he wants to make sure he's clear with you, you knew about the program before I filed the lawsuit on your behalf; right?

THE WITNESS: Yes.

MR. ELLISON: He wants to know when -- before filing the lawsuit when did you first learn about the newborn screening program and the biotrust program and the blood program.

**A I don't know the exact date, so --**

MR. ELLISON: So when we're talking about filing the lawsuit, he's talking about when -- not when you necessarily but when I filed the lawsuit on your behalf.

Does that clear up the time line for you?

THE WITNESS: Yeah.

MR. ELLISON: Okay. Aaron, that's where I think -- you're using lawyer language and she's not a lawyer, so --

MR. LEVIN: Okay. Thank you.

Q With that in mind, prior to your attorney filing the lawsuit in I believe it was February 2018 -- so you already indicated prior to that you learned about the newborn screening program, by which I'm referring specifically to the heel prick test, at the hospital from hospital staff?

**A (Nodding head in affirmative)**

Q I guess first question, is that all still correct?

**A Yes.**

Q So with all of that background in mind, when did you first learn about the State or -- yeah, the Department of Health and Human Services retaining blood spots?

**A That would have been when Phil and I have talked is when I learned that they retained it.**

Q So it would have been it sounds like shortly before your attorney filed a lawsuit?

**A Correct.**

Q And then I was asking if --

**A (inaudible)**

Q I'm sorry? Go ahead.

**A Yes, go ahead. No, that's okay.**

Q So then I was also asking if prior to your attorney filing the lawsuit did you do any research regarding any aspect of either the newborn screening program or separately the biotrust retention program?

**A I did a little bit, yes.**

Q How did you do that?

**A Online.**

Q Do you remember what you were looking into at that time, if it was the testing portion or the retention portion or both, or neither?

**A I don't remember exactly.**

Q Okay. Do you remember if you ever contacted the Department of Health and Human Services?

**A No, I did not.**

Q You remember that you did not?

**A Correct.**

Q Have you done any additional research or contacted the Department after the lawsuit was filed by your attorney?

**A No.**

Q What concerns do you have about the Department of Health and Human Services retaining blood spots?

**A That they are withholding -- how do I want to word it? They're withholding the -- like they can hold that but then they have no way of using regulations of who's going to get**

**a hold of that blood and, you know, who's going to use that blood for what. It --**

Q Did you ever -- I'm sorry. Go ahead.

**A So there's no regulations on what's going to be done with that blood.**

Q Have you done any research into what regulations or privacy protections may exist?

**A A little bit.**

Q What have you found?

**A I don't have all my stuff here right now.**

Q Just to the best of your memory.

**A I don't know right now.**

Q Do you recall if you found that there are any privacy protections in place from the Department?

**A I don't know.**

Q What are you hoping happens to your children's blood spots at the conclusion of this lawsuit?

MR. ELLISON: Objection; calls for a legal conclusion. But go ahead, Lynette, and answer.

**A Discarded.**

Q So you would like to see your children's blood spots destroyed?

**A Correct.**

Q Are you aware that the Department of Health and Human Services will destroy your blood spots on request?

**A Yes.**

Q So I am going to -- yes, I can share my screen and I am going to show you some documents.

MR. LEVIN: Bear with me.

(Counsel shares document on screen)

Q I don't know if -- I tried to share my screen. Can you see that?

**A Yes.**

Q I am going to -- I'm going to try to get the whole page visible. Can you see that whole page?

MR. ELLISON: Aaron, before you go into this I have an objection to this, to you producing this.

MR. LEVIN: Okay.

MR. ELLISON: I don't want to give a speaking objection as to what my concern is because my concern may affect the question. So if you would permit me I'd like to make the objection, you ask about it and I can explain why. Unless you want me to go ahead? Because I'm afraid I'll be tipping the witness to my concern.

MR. LEVIN: No, that's fine. We can do it that way.

MR. ELLISON: Which way?

MR. LEVIN: I can ask some questions first and note that you have an objection and we can hash it out later.

MR. ELLISON: Okay. Very good.

MR. LEVIN: I'm okay with that.

MR. ELLISON: Okay. Go ahead then.

Q Have you seen this form before?

**A No.**

Q Then I'm going to ask you to just take a minute, however long you need, please review the form and let me know when you've had a chance to read it. And let me know if you need me to zoom in or out or anything.

(Witness reviews exhibit)

**A Okay.**

Q So you indicated you were aware that you could have your children's blood spots destroyed, but you've never seen this form before?

**A That's not what I said.**

Q I'll break that down and I'll ask two questions.

**A (inaudible)**

MR. ELLISON: Lynette, make sure that -- I'm just going to direct you. I know we're struggling with the Internet world but make sure you give a pause to when these guys are talking one at a time so that we can get it on the record. Okay?

THE WITNESS: Oh, sorry.

MR. ELLISON: No problem. Don't worry about it.

THE WITNESS: Yeah, sorry.

MR. ELLISON: It's just we do that occasionally. Go ahead, Aaron. I apologize, go ahead.

Q So I asked earlier if you are aware that you may request that the Department of Health and Human Services destroy your children's blood spots. I was under the impression you answered that you were aware; is that correct?

**A I wasn't aware I thought.**

Q Okay. So you --

**A I wasn't --**

Q So as we sit here today it would be new information for you that you may request the Department of Health and Human Services destroy your children's blood spots?

**A Correct.**

Q So you've had a chance to read this form?

**A Yes.**

Q So I suspect there's an objection coming to this question so we'll all talk a little bit slowly. Having reviewed this form, does it appear that if you were to fill this out you could have your children's blood spots destroyed?

MR. ELLISON: Lynette, I'm going to object on the basis that it calls for a legal conclusion, and I'm also going to place my objection from earlier that this form was not available and nor was it made available to the witness prior to because it was -- the last revision on this was February of 2019, after this lawsuit had been commenced. So

this question is irrelevant and lacks foundation.

Q With all of that being said, please still answer the question.

MR. ELLISON: Yup, go ahead, Lynette, you may answer.

**A Okay. Sorry. Can you repeat the question now? Sorry.**

Q I can.

MR. LEVIN: And I'll just note that those objections have been made and are continuing into this question so that we're not stopping and doing that again.

Q So having had the opportunity to review this form, does it appear that if you were to fill out this form today you could have the Department of Health and Human Services destroy your children's blood spots?

**A Yes.**

Q Have you requested the destruction of your children's blood spots?

**A No.**

MR. LEVIN: So this is -- I think just for the attorneys maybe, it's marked Exhibit A. I've got one document right now with all my exhibits and they're all marked a little bit differently on the bottom. So I am going to scroll down to my next one and I'll just send this around to everybody. But I'm going to move now to what I've marked as Exhibit B.

(Counsel shares document on screen)

Q Can you see that?

**A Yes.**

Q Do you need me to zoom in? It looked like you were leaning a little bit closer to your screen.

**A No, I'm okay.**

Q So take a minute and review this for me, please, and let me know when you're done.

(Witness reviews exhibit)

**A Okay.**

Q Have you seen this before?

**A Obviously but I don't remember.**

Q You say "obviously," why obviously?

**A It's my signature.**

Q So that is your signature at the bottom -- or towards the bottom?

**A Yes.**

Q Do you see in the top left, does it say "Michigan BioTrust for Health"?

**A Yes.**

Q And you've acknowledged that's your signature, you have no reason to dispute that that's not your signature?

**A Correct.**

Q I'm going to move now to my next exhibit, which I've marked C.

(Counsel shares document on screen)

Q And if you could read this and let me know when you're done.

(Witness reviews exhibit)

**A Yes.**

Q Do you recognize this?

**A Yes.**

Q Does that appear to be your signature on the form?

**A Yes.**

Q Does this one also say "Michigan BioTrust for Health" towards the top on the left?

**A Yes.**

Q I'm going to move now to my next exhibit, which I've marked D.

(Counsel shares document on screen)

Q And if you could also take a moment to review this and let me know when you're done.

(Witness reviews exhibit)

**A Yes.**

Q Do you recognize this form?

**A I recognize the signature.**

Q Is it your signature?

**A Yes.**

Q Does this form also say "Michigan BioTrust for Health" on it?

**A Yes.**

Q So on this form -- yeah, this form looks a little bit different from the last two. In the middle are there two boxes, one that says, "Yes, my baby's blood spots may be used for health research" and one that says, "No, they may not be used for research"?

**A Yes.**

MR. ELLISON: I'm going to object to the statement, it does not accurately reflect the wording that's on the form.

MR. LEVIN: I did paraphrase the second box.

MR. ELLISON: Fair enough. As long as we recognize that I'm okay with that.

MR. LEVIN: Yes, I paraphrased the second box. I will be more technical if I do this again.

Q But in general there are two boxes, one says "yes" one says "no"?

**A Correct.**

MR. ELLISON: Same objection.

MR. LEVIN: Same objection, fair enough.

Q Can we agree that there's an "X" in the box next to -- and now I'm reading it -- "Yes, my baby's blood spots may be used for health research. This applies to all blood spots collected for newborn screening"?

**A Yes.**

Q And I'm not sure I asked it for this form, no reason to

dispute that that's not your signature -- or that is your signature? Sorry. Let me rephrase. Do you have any reason to dispute that that is your signature?

**A No.**

Q I have one more exhibit, I've marked it E.

(Counsel shares document on screen)

Q Please review this one. And I'm going to zoom in a little bit because I can't see it. Let me know if that messes with your ability to read it. Please let me know when you've had the chance to review it.

(Witness reviews exhibit)

**A Correct; yes.**

Q All right. So let's start again with the signature. Does that appear to be your signature?

**A Yes.**

Q Do you have any reason to dispute that that is your signature?

**A No.**

Q I may need to zoom in, but does it appear as well on the top of this form that it says "Michigan BioTrust for Health"?

**A Yes.**

Q Can you see it -- sorry, I was talking over you.

**A Yes, I can. I zoomed in.**

Q So this one also has two check boxes, they're much wordier than the last one so I'm going to speak in -- I'm going to

read just the bold face at the top of each box and not the entire box. Does the top portion of the form have a check box next to -- and this is just the box that I'm asking about -- "Yes, my baby's blood spots may be used for health research through the BioTrust"?

**A Correct.**

Q And then lower it has one next to, "No, my baby's blood spots may not be used for health research"?

**A Correct.**

Q Is there an "X" next to the -- or inside the box next to, "No, my baby's blood spots may not be used for health research"?

**A Yes.**

Q So we've looked at these four documents -- so let me ask it this way: Do you have any reason to believe that your children's blood spots have been used for any purpose by the Department of Health and Human Services?

**A I don't know.**

MR. KENNEDY: Aaron --

MR. LEVIN: Do you want us to pause for five minutes?

MR. KENNEDY: If that's okay.

MR. LEVIN: Yeah; yeah, that's fine.

MR. KENNEDY: Great. Thank you.

MR. LEVIN: So we will take a short break.

(Off the record)

Q So I'm going to go -- I should have asked this earlier, so we're going to go a little bit out of order. The other thing with depositions is sometimes we ask silly questions because we want to have it in writing. So bear with me. How many children do you have?

**A Four.**

Q So you indicated at the beginning that hospital staff -- let me rephrase that. You indicated that around the time of delivery hospital staff informed you about the newborn screening program. Do you recall if that was around the time of delivery of your oldest child?

**A Yes. It was when they came in just to do the -- collect the blood though.**

Q But it was your oldest child?

**A Yes.**

Q So now I'm going to go back to -- we looked at four forms before our break. I think -- the parties I think generally disagree over what effect these forms should be given. I am going to call these forms, just as a group, consent forms. So we had the chance to review those?

MR. ELLISON: Are you asking me or Lynette?

Q I'm sorry. Ms. Wiegand.

MR. ELLISON: Lynette, I think what he's asking is we just -- those forms we're talking about, he's calling

those the "consent forms." Okay?

THE WITNESS: Oh.

MR. ELLISON: Do you understand that?

THE WITNESS: Oh. Yes.

MR. ELLISON: Okay.

Q Is my screen still sharing?

**A No.**

Q Okay. Let me try that again.

(Counsel shares document on screen)

Q How about now?

**A Yes.**

Q So before we went off for a couple of minutes I believe my question was do you have any evidence that your children's blood spots have been used for any purpose by the Michigan Department of Health and Human Services?

**A No.**

Q Do you have any evidence that your children's blood spots have been used by anyone else?

**A No.**

Q So I'm going to go back to my Exhibit B, which you should be able to see right now, it should have a little "B" on the bottom right.

**A Yes.**

Q Have you had the chance to review this form?

**A Yes.**

Q Do you have any reason to believe that -- so I'm going to draw your attention to the date on this form, and I'm trying very carefully to be a little bit vague when I refer to your children. But do you have any reason to --

MR. ELLISON: Aaron, just for the record, I did explain to her about the Rule 17 issues with Federal Court so she's aware of that, so --

MR. LEVIN: Okay. Thank you.

Q So based on the -- I'm still thinking about how I want to ask this question. Sorry. Do you have any reason to believe that the blood spots referred to by this Exhibit B form have been used contrary to what it says on this form? Does that make sense?

**A Can you repeat that?**

Q Sure. So based on the date on this form I will tell you that it appears to me that this form is in reference to the blood spots retained from one of your children born on or about, or approximately, November 22nd, 2011. My question --

**A Correct.**

Q -- do you have any reason to believe that the blood spots retained from this birth have been used in any way not directed by this form -- or not authorized by what this form says? I expect there's going to be an objection, but in any way not authorized by what this form says?

MR. ELLISON: Lynette, I'm going to object on the basis that the question is asking for a legal conclusion asking about authorization of what this form provides for, which goes to the heart of this case. But, Lynette, answer him as best you can.

A **Can I say I don't know? Because I'm confused.**

Q I'll try again.

A **Sorry.**

Q No that's all right; that's all right. I will try again. So let's try it this way -- I think I'll just ask it again with the objection noted and continuing. Do you have any reason to believe that the blood spots this form references have been used for any purpose?

A **I don't know.**

Q Why don't you know?

A **I don't know if they have been used.**

Q Do you have reason to think they have been?

A **How would I know if they have been used?**

Q So other than the possibility existing, have you seen anything, reviewed anything, been given any reason to think that they've been used?

A **I haven't been contacted, if that's what you're asking.**

Q That's not what I'm asking. Do you have any reason sitting here today to believe other than the possibility existing that they've been used?

**A I don't know.**

Q Do you not know because you've been given no indication -- or you've seen no indication that they have been?

**A Like until I know something has been done there's always going to be that "if."**

Q So I understand there's if, I'm asking if you've seen anything more specific than the possibility existing?

**A I have not.**

Q Okay. Looking at Exhibit B -- and again noting the objection -- is that consistent with this form?

**A Is what?**

Q I'll try another way.

**A Sorry.**

Q All right. I'm going to move away from the forms for a moment because I don't think we necessarily need that right now. So moving away from the documents. Do you have any reason to believe that information relating to your children's blood spots have been accessed by anybody from the Department of Health and Human Services storage program?

**A Not that I'm aware of.**

Q So now I am actually going to go back to the forms, but I'm going to ask a different question. So I'm looking at Exhibit B, can you still see that?

**A Yes.**

Q So I think there may be an objection, but I'm going to ask

the question and I think it will be one you will ultimately answer. So there's a box in the middle of the page; correct?

**A Yes.**

Q And towards the bottom of that box it says,

"I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening."

Is that correct?

**A Yes.**

Q And you've already acknowledged that that is your signature below that; right?

**A Yes.**

Q I'm going to now go to Exhibit C, does that appear to be the same form?

**A Yes.**

Q Same language in the bottom of that box?

**A Yes.**

Q Still your signature?

**A Yes.**

Q So now I'm going to go to Exhibit D, this is a different version of the form. We talked about this one already -- the differences already. But there is an "X" in the box next to, "Yes, my baby's blood spots may be used for health

research"?

**A Yes.**

Q And that is your signature at the bottom?

**A Yes.**

Q So now I'm going to go to Exhibit E, this one has an "X" in the box next to, "No, my baby's blood spots may not be uses for health research"; correct?

**A Correct.**

Q And that is your signature at the bottom?

**A Correct.**

Q So my question, with all four of these in mind, did you -- after this form -- strike that. My question, at any time have you considered changing the permissible uses for your children -- for the blood spots from your children born prior to 2017?

**A No, my mind set was always the same.**

Q So I'm going to go to Exhibit D. Can you see that?

**A Yes.**

Q There's a checkmark next to the box that says, "Yes, my baby's blood spots may be used for health research"; correct?

**A Correct.**

Q My question is, at any time did you consider contacting the Department of Health and Human Services to have what I'm representing as a "yes" on that form changed to a "no"?

**A I -- I don't remember that form being filled out.**

Q Which one?

**A The one that's dated 2014.**

Q Okay. I'm scrolling now back to Exhibit C, which is marked 2013 -- which is dated -- sorry -- 2013. Did you ever consider changing the authorized uses for the blood spots referred to by this form?

**A I didn't --**

MR. ELLISON: Hold on a second. I'm going to object to the form of the question that it asks about -- it presumes authorized uses. However, Lynette, go ahead and answer if you can.

**A I didn't know -- like I guess how it was explained to me that it was automatic, we didn't have a choice from how it was explained to us. So I don't know how to exactly answer that.**

Q What was automatic -- or what was explained to you as being automatic?

**A The nurses, they said we have to do this, we have no choice.**

Q Do what? What is "this"?

**A Take the blood.**

Q I'm asking about storage though. I'm not asking about taking the blood.

**A I guess -- no, I haven't contacted anybody, because I --**

Q Okay. So I'm going to go back to Exhibit E -- actually I've

already asked that, I don't need to ask that again. Has the fact that these blood spots were retained interfered with your ability to determine medical care for your children?

**A No.**

Q Do you recall if you were ever given an educational pamphlet or brochure explaining either the newborn screening program or the biotrust program?

**A I might have in like our OB/GYN binder that we were supposed to do on our own time, but that was on our own free will.**

Q Do you remember what year that would have been?

**A I don't with four kids.**

Q Fair enough.

MR. LEVIN: I think that is everything I have at the moment. So, Jeremy, I believe we've been doing you next on these if you have anything.

MR. KENNEDY: Thank you. Good morning, Ms. Wiegand. My name is Jeremy Kennedy. I'm the attorney for Dr. Antonio Yancy, the executive director of the Michigan Neonatal BioBank. I just have a few questions for you because I think Mr. Levin has asked most of the questions that I would have asked. So we can hopefully keep this brief.

EXAMINATION

BY MR. KENNEDY:

Q Prior to this lawsuit had you ever heard of the Michigan

Neonatal BioBank?

**A In depth, no, but on forms obviously; but in depth, no.**

Q And prior to filing this lawsuit what was your understanding of what the BioBank does?

**A Before the lawsuit I didn't know about them, to be honest.**

Q And do you have an understanding of what they do as we sit here today?

**A I have some better from what Phil and I've talked.**

Q Without telling me anything that your attorney has told you, what do you believe the BioBank does?

**A Well, from what Phil and I've talked I --**

Q I don't want to know, you know, any specifics of what Mr. Ellison has told you or anything like that.

**A Right. That's why I'm kind of -- that's kind of where most of my information has come from, so I'd prefer to not --**

Q So is it your understanding that the BioBank stores the dried blood spot cards?

**A Yes.**

Q And are you aware of the BioBank -- are you aware of whether or not the BioBank does anything else with the dried blood spot cards?

**A I don't -- I don't know.**

Q Okay. Have you ever spoken with anyone at the BioBank about your children's blood spot cards?

**A No.**

Q Have you ever spoken with anyone at the BioBank regarding anything the BioBank does?

**A No.**

Q Now, you said earlier when I believe Mr. Levin asked that you'd like your children's blood spot cards to be destroyed; is that correct?

**A Correct.**

Q Is there anything else you are seeking in this lawsuit?

MR. ELLISON: Objection; calls for a legal conclusion and the analysis of complaints. But go ahead, Lynette.

**A Thanks, Phil.**

MR. ELLISON: He just wants to understand what is it that you're looking for. So go ahead and explain to him as a lay person.

**A I know that mine is, you know, the -- to make it known exactly, you know, the steps and everything -- what's being done. And then, yes, I want ours to be destroyed now.**

Q I'm sorry. I didn't quite catch what you said at the first part. Was it to make --

**A To be able to have the options, you know, to have the blood collected or not, you know, in the beginning of that newborn stage.**

Q And why is that?

**A That should be a parental I would think versus --**

THE WITNESS: I don't know if I should say that, Phil.

MR. ELLISON: Go ahead and explain to him what your understanding is and what your goals are here.

A **Like I think a parent should be able to say, you know, for like the blood born stuff that a parent should be able to say "yes" or "no" to that newborn screening, that the blood should or should not be a parent's choice.**

Q Because why?

A **Because, like, I didn't want to do it and the nurse said, no, we have to do this or I lose my job. So that's why the forms before that last form the reason why I signed is because the nurse said you need to sign this or I lose my job is how it was explained.**

Q And I'm sorry, what child was that for? Which -- in birth order one, two, three or four?

A **For the one that -- from my last one that I was able to put the "no," that's the one I know I said "no." The third one I -- I don't remember that form. I was medicated, I don't remember that labor. And I filled that form out the day after he was born and I was still drugged, the medications were still in my system. I don't remember that form, but it is my signature. And the other two I signed, yes. But that's how it was explained in the hospital.**

Q So why would you not want the screening done?

**A It shouldn't -- no, I didn't say that. I just said it should be optional for a parent to choose, not mandated.**

Q And why is that, in your opinion?

**A Because it should be a right, it shouldn't be a governmental thing. You should have the right to choose.**

Q Now you said you --

**A And you should do it before you deliver, not after you deliver and after you've been having medications given.**

Q You said you were still drugged for the birth of your third child, was that a natural birth or C-section?

**A Natural.**

Q What time of day was the child born?

**A First thing in the morning; they gave me medications the night before.**

Q Was it a long labor then?

**A Just overnight. I slept and they woke me up and that's all I remember. The pictures of me and my son I look God awful.**

Q How long were you in the hospital?

**A Two days.**

Q And the form was filled out on the second day?

**A He was born the 24th and the form was filled out the 25th.**

Q And what kind of medication did they give you?

**A I have no idea. It was something to make me sleep I believe. But even the doctors were like, "Welcome back, you had us scared."**

Q Why was that?

**A Because I didn't respond to nothing.**

Q Was your health ever in danger with that pregnancy -- that birth?

**A Not that I know of. I don't remember much of that hospital stay. I don't even remember being discharged or anything like that. When you usually get discharged you remember, you know, the happy stuff of leaving and -- I don't have memories of even delivery.**

Q And you have never requested the blood spot cards be destroyed; correct?

**A No. I was unaware of that form.**

MR. KENNEDY: I think that's all I have.

MR. LEVIN: So I know this would be out of order. I have a little follow-up. I can do that first if you want to have that ahead of time or I can wait until after you go.

MR. ELLISON: That's fine. Go ahead, that's fine.

EXAMINATION

BY MR. LEVIN:

Q So you indicated a few minutes ago that you think parents should have the opportunity to say "yes" or "no"; correct?

**A Correct.**

Q So I have shown you a couple of forms that I am representing have "yes" and "no" on them; correct?

**A Correct.**

Q Do you have any reason to believe that in general if a form is marked "yes" or a form is marked "no" the Department of Health and Human Services does not follow that?

**A I assume they do, but you should have that form filled out before somebody is medicated.**

Q But you assume that the State follows what people request on these forms -- or direct on these forms?

**A Yes.**

MR. LEVIN: Okay. That's all I have.

MR. ELLISON: Lynette -- Aaron, can you scroll back up to Exhibit B?

MR. LEVIN: Which one was that?

MR. ELLISON: Exhibit B as in boy?

MR. LEVIN: Oh, sorry, I didn't mean to leave these up this whole time, but if you need it --

MR. ELLISON: No, that's fine because I actually need them.

EXAMINATION

BY MR. ELLISON:

Q Lynette, this form, as you indicated, had your signature on it and it's for your child born November of 2011. And for purposes -- that would be your child with the initials LRW; correct?

**A Correct.**

Q The time when you were in the hospital, were you ever

presented with a brochure explaining -- I want to be clear about two different things, one is about the heel prick test and the newborn screening program?

**A No.**

Q And secondarily, were you ever given a brochure or information about the Michigan BioTrust or the Michigan BioBank?

**A No.**

Q Did the doctors or medical staff when presenting to you with this form discuss with you the risks and benefits of participating in the Michigan BioTrust program?

**A No.**

Q As Mr. Levin has pointed out, there's -- right above your signature there's a statement that says, "I voluntarily agree to allow my child's DBS to possibly be used for medical research." Did anybody at the time that you were signing this document or prior to you signing this document explain to you what medical research was?

**A No.**

Q Sitting here today do you have any understanding as to what the scope of what medical research actually means?

**A No.**

Q Knowing what you now know about the newborn screening program and the Michigan BioTrust and the Michigan BioBank, would you consent to this program today if you were sitting

in the same shoes you were back in November of 2011?

**A No.**

MR. ELLISON: Aaron, can you scroll down to Exhibit B -- or excuse me -- Exhibit C.

Q All right. This is your child born in July of 2013, which I have as the initials CJW.

**A Correct.**

Q Right?

**A Yes.**

Q Okay. Again, looking at this form you've indicated earlier that this form is similar to the one for the previous child and it has the same language as the medical research. When you signed this document did anyone from the hospital or anyone on behalf of the State or the BioBank or the BioTrust explain to you what medical research means?

**A No.**

Q Did anyone from the hospital, from the BioBank or from the State, explain to you the risks or benefits of participating or consenting to be part of this particular program?

**A No.**

Q And I notice the date on this document is the day following the birth of CJW. Do you remember what time of day CJW was born?

**A Evening.**

Q Evening as in dinnertime or later?

**A He was just after 7:00 -- sorry -- he was just after 10:00, so late evening.**

Q Okay. Do you remember when anyone from the hospital or whoever presented to you with this form came to you and -- let me ask it this way: This form is dated 7/18, which would be the following day, do you remember what time of day that form was signed at all?

**A I don't remember the time, but they had me sign -- all the papers -- the only one I don't remember for sure is the one for 2014, but for all of them they were all signed at the time of the blood being done. So when the blood was done is when the nurse had me sign. When they were taking the child they said, "Sign this form," and then that's when they either did the prick in the room or they took him to the nursery to do the testing.**

Q Again, knowing what you -- let me ask this: In Exhibit C there is a checkmark in the top right-hand corner that says, "Information provided to parent," where there's a checkmark.

**A That I did not do.**

Q You didn't put that mark on that particular form?

**A No.**

Q Do you know what information was provided to you? Do you recall what information was provided to at all, if any?

**A No.**

Q As a mother of four and as a -- someone whose gone through

this process at least four times, would there be a more ideal time to present medical decision-making in your opinion rather than at the time that these have been presented to you following the birth of your children?

**A I would recommend either do it in -- like in an assigned like class or an OB appointment or something that is done at one of the appointments or something.**

Q Would it be better, in your opinion, that this information and these questions and this request for consent be done before the birth of the child?

**A Absolutely.**

Q Would you feel that you would have a better understanding and a better opportunity to grasp and ask questions and be able to grasp what's actually being asked of you if it had been asked to you before the birth of the children?

**A Yes.**

Q Again, looking at this I don't see the words -- do you see the words Michigan Neonatal BioBank anywhere in there? I don't see BioBank in there.

**A No.**

Q Were you informed at the time about the Michigan Neonatal BioBank, in July of 2013, to the best of your recollection?

**A Not that I know of, no.**

Q Were you ever informed or told that the blood spots would be stored indefinitely at a warehouse in Detroit, Michigan for

use by third parties and researchers?

**A No.**

Q All right. When it says here it will be used for medical research, was there any indication to you or any information given to you as who would be conducting medical research?

**A No.**

Q Would it be fair to say that after you'd just given birth to a child medical staff threw a form in front of you and you just signed it? Would you agree with that?

**A Yup; yes.**

MR. ELLISON: If we can go to Exhibit D.

Q Exhibit D is the form for your child born on -- almost a Christmas baby here it looks like -- 12 of 2014 with the initial HJW; correct?

**A Yes.**

Q Again, looking at this form, as Mr. Levin has pointed out this is a different form than the previous two children, and I note here that it has a checkmark next to, "Yes, my baby's health spots may be used for health research," rather than medical research. Did anyone explain to you what the difference was between health research versus medical research as provided in the prior forms?

**A No.**

Q All right. And at the time of the birth of HJW did anyone at the hospital explain to you the risks and benefits of

participating in the Michigan BioTrust or the Michigan Neonatal BioBank?

**A No.**

Q Did anyone present you -- I notice on here there's reference to a brochure. Did anyone give you a brochure at the time that you were signing this document?

**A No.**

Q Did anyone go over a brochure with you and walk through it with you the different details of the BioTrust and/or the BioBank program?

**A No. That one -- none of that birth I remember, Phil.**

Q Okay. This is the one where you said you were heavily medicated?

**A Yeah, this is the one I don't -- yeah.**

Q Was your husband available at this time of the birth of these -- and I know we're on the third child right now here. But was your husband available to provide consent during the birth of these three prior children?

**A He was there for all the births.**

Q Okay. Is there any reason you know why the State or the medical professionals or the BioBank didn't ask your husband for consent?

**A No.**

Q Knowing what you know now about the BioTrust program and as part of the details we've learned as part of this lawsuit,

would you have checked the "yes" box today -- or then if you know what you knew today?

**A No.**

MR. KENNEDY: Objection; calls for speculation.

Q Go ahead, Lynette.

**A No.**

MR. ELLISON: If we can scroll to the next one, to Exhibit E.

Q And this is your child with the initial MLW born January 30th, 2017. And I note this document is also dated the same day; correct?

**A Yes.**

Q All right. Again, looking at this document, this one is different than the previous versions that we saw earlier. And in the box checked "no" they said, "My baby's blood spots may not be used for health research." Did anyone at the hospital, from the State or from the BioBank explain to you what was meant by "health research"?

**A No.**

Q Looking next to the "yes" box, it says, "My baby's blood spots may be used for health research through the BioTrust." What did you -- did you -- let me ask it this way: Did anyone from the hospital, the State or the BioTrust or the BioBank explain to you what sorts of things were involved with the health research through the BioTrust?

A **No.**

Q Did anyone present you with a copy of a brochure or an informational packet explaining to you the risks and benefits of participating in the BioTrust program?

A **No.**

Q Did anyone -- I'll say setting aside brochures or written material, did anyone verbally or orally discuss with you the benefits and risks of participating in the BioTrust program?

A **No.**

Q Did you understand at the time when you were signing this document that by saying "no" that the State was still going to retain your child -- let me get the initials -- MLW's blood indefinitely?

A **Nope.**

Q And again, do you remember what time of day this child was born at?

A **She was mid evening.**

Q And this form, again -- I think you've answered this but bear with me. This form was presented to you after the birth of your child; correct?

A **Correct.**

Q So after the birth, at some point shortly thereafter, they're presenting you with these legal documents and forms for you to sign and make decisions on; correct?

A **Correct.**

Q Do you feel sitting here today looking at all four of your children and all the different various forms that you had that you had sufficient and clear information at the time you signed these documents to make an informed choice about the Michigan BioTrust program and your children's participation with it?

**A No.**

MR. KENNEDY: Objection; calls for a legal conclusion.

Q Go ahead, Lynette.

Q No.

MR. ELLISON: Okay. Thank you for your time today. These guys might have some follow-ups with you, but that's all the questions I have. I reserve the balance of our testimony for affidavit and testimony at trial. Thank you.

MR. LEVIN: Jeremy, do you have any follow-up?

MR. KENNEDY: Briefly.

EXAMINATION

BY MR. KENNEDY:

Q Ms. Wiegand, are you aware of any of your children's blood spots being uses for research of any type?

**A I don't.**

MR. KENNEDY: Thank you. That's all.

MR. LEVIN: I don't think I have anything else.

Thank you for your time today.

(Deposition concluded at 11:23 a.m.)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 28

## Elizabeth R. Eisenhauer, *Mothers' Decisions About Donating Newborns' Blood Spots for Research*, 33 J. Perinat. Neonat. Nurs. 361 (2019)

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# Mothers' Decisions About Donating Newborns' Blood Spots for Research

## *A Qualitative Study*

Elizabeth R. Eisenhauer, PhD, RN; Alan R. Tait, PhD; Lisa Kane Low, PhD, CNM, FACNM, FAAN; Cynthia M. Arslanian-Engoren, PhD, RN, FAAN

**ABSTRACT**

Residual dried blood spots from millions of newborns are being stored and used for research. The state of Michigan proactively developed a broad consent process for research use of newborns' blood spots. However, the extent to which mothers make informed choices about this research is unclear. A descriptive, qualitative study was conducted examining this issue. Twenty-nine observations of the consent process and 20 semistructured interviews were conducted with mothers on the postpartum unit of a large, academic hospital in Michigan. Content analysis of the transcripts was conducted. While most mothers agreed to donate the blood spots ($n = 14/20$; 70%), findings indicated that most decisions were uninformed ($n = 16/20$; 80%), as mothers lacked knowledge of biobanking research. Misunderstandings about anonymity, the consenter's credentials, and entity conducting the research seemed to influence decision making. Suggestions for improving the consent process include (1) changing the venue of blood spot education and consent from the postpartum period to the perinatal period, (2) strengthening the depth of information and delivery of information provided about the topic, including ethical and values clarification, and (3) increasing consenter education and training. Implementation may help increase the proportion of informed decisions.

**Key Words:** biological specimen banks, ethics, informed consent, newborn blood spot screening, nurses

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Residual dried blood spots (rDBS) are biospecimens that remain after legally required newborn screening (NBS) is completed on the nearly 4 million infants born annually in the United States.[1,2] The rDBS are frequently stored and used for research, often without parental consent.[2] The collection of human biological specimens for future, unspecified research (ie, biobanking) has become a widespread practice.[2,3] By retaining, storing, and distributing rDBS, NBS programs, managed by state departments of health, are a major source of pediatric biospecimens for research.[4] While this research has led to important medical advancements,[5] it has also introduced new ethical issues including risks to genetic privacy and other personal values.[4,6-8]

Taking note of ethical concerns, in 2010, the Michigan Department of Health and Human Services (MDHHS) was the first to adopt a broad consent process for rDBS research as part of the NBS that occurs about 24 hours after birth.[9] However, because broad consent provides few details about future research, it

may not provide adequate information for informed decision-making[10] and thereby could contribute to decisional regret and moral distress.[11] Thus, it is also essential to determine whether donors (or surrogate decision makers such as parents) possess adequate knowledge and understanding of biobanking to make an informed choice.[12] As NBS and rDBS research occurs globally, this concern has international implications.[13]

## BACKGROUND

### Genetic privacy

It is important for individuals to understand the risk for a potential breach of genetic privacy before donating biospecimens to a biobank.[14] Deoxyribonucleic acid (DNA) in biospecimens reveals individuals' unique attributes and genetic predispositions to a host of diseases, including many that potentially carry social stigma (eg, schizophrenia, alcoholism).[15] Unwanted exposure of private genetic information may cause personal embarrassment, distress, or discrimination (eg, employment, insurance, or social) despite partial protective legislation.[15,16] Because DNA is unique to each human, replacing names, birth dates, and other identifiers with a code may not fully protect genetic privacy.[15] In addition, without specific (or in some cases any) consent, rDBS have been used to study issues such as maternal cocaine and tobacco use,[17,18] which may also be perceived as an invasion of privacy.

### Moral risk

Because intended research uses of rDBS are often unspecified at the time of donation, alignment of the research with personal values may be unclear or unknown. This lack of clarity may precipitate moral risk, defined as the possibility that biospecimens may be used in research activities misaligned with the parents' (or donors') personal, religious, or cultural values.[7,8,15] A recent literature review noted several religious concerns related to biobanking including blood storage, cloning, and genetic analysis.[19] Lack of transparency, at the time of consent, about potential uses for biospecimens may pose conflicts with personal values and lead to moral distress.[11]

### Theoretical framework

The multidimensional measure of informed choice[12] (hereafter MMIC) was the theoretical framework guiding this study (see Figure 1, derived from Marteau et al.[12]). The main concepts are knowledge, attitudes, and the participation decisions. Knowledge is defined as participants' understanding of key information about

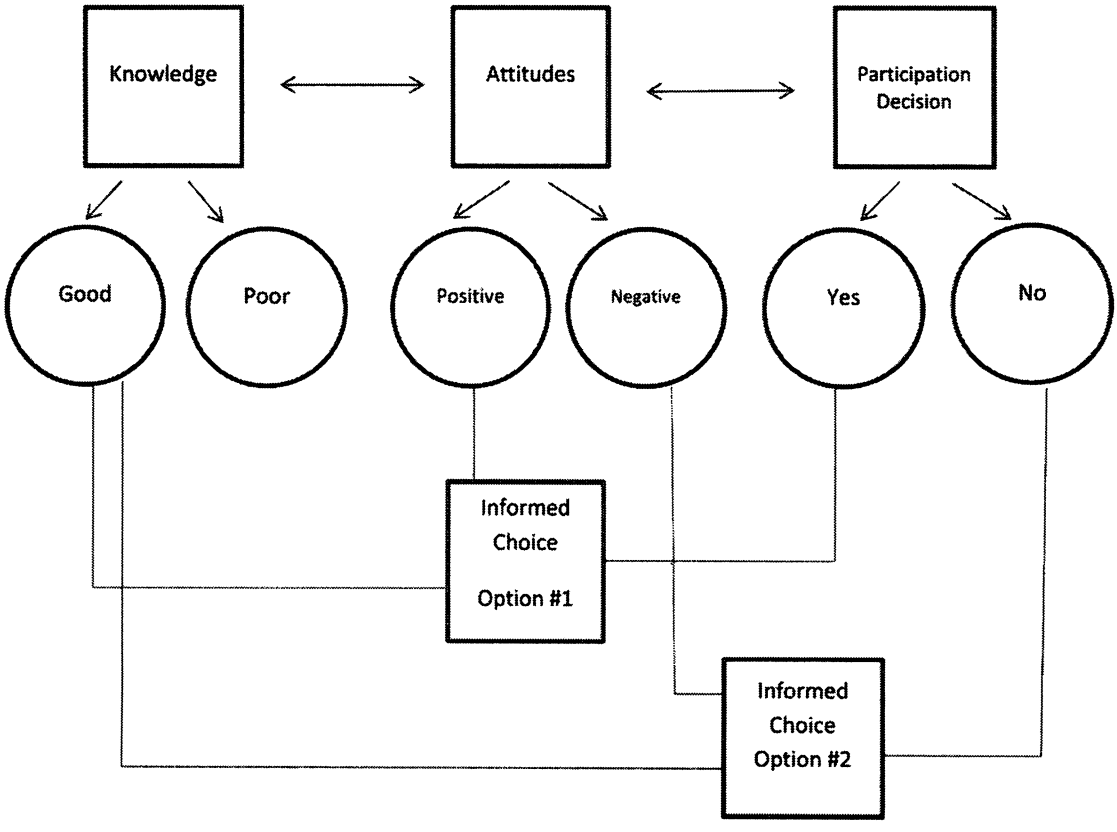


**Figure 1.** Informed choices per the multidimensional measure of informed choice.

the topic, deemed essential by professional consensus for making an informed choice. Attitudes are individuals' value-based judgments about facts and information.[12] In this model, an informed choice is based on adequate knowledge and consistent with decision makers' personal values, as reflected by their attitudes.[12] While the MMIC has often been used in studies about prenatal testing,[12,20,21] to our knowledge, this is the first study to use it to guide the examination of mothers' decisions about donating newborns' rDBS for research.

## METHODS

### Design

This article presents the qualitative component of a larger triangulated study[22] conducted to investigate factors influencing mothers' decisions to donate their newborn's rDBS to the Michigan BioTrust for Health (ie, "the BioTrust"). This program of the MDHHS is charged with oversight of the research use of rDBS, including the consent process.[9] The specific aim of the qualitative portion of the study was to describe the context and content of the consent process, mothers' knowledge of the BioTrust and biobanking, and the influence of personal and religious values on their decisions to donate their newborn's rDBS for research purposes. Furthermore, this study sought to determine the proportion of decisions deemed informed choices, as measured by the MMIC.[12] A descriptive, qualitative design[23] was used to characterize factors that influenced these decisions, including the context of the postpartum unit, mothers' knowledge of biobanking, their personal values, experience with the consent process, and demographic characteristics.

### Setting and sample

The BioTrust consent process occurred in private rooms on the mother/baby unit of a large, academic medical center; the unit has 50 private maternity rooms and delivers nearly 4000 newborns each year. A convenience sample was recruited by the principal investigator (PI) as mothers were approached by hospital personnel about NBS and consent for rDBS research. The PI shadowed the staff member responsible for obtaining BioTrust consent (ie, "the consenter"). When the consenter approached each mother to explain NBS and the BioTrust, she also explained the PI's presence. Verbal permission was obtained from each mother for observation of the BioTrust consent process. After the mother rendered a decision about the BioTrust, the mother was asked to participate in a brief semistructured interview regarding her decision. To be eligible to participate in the semistructured interview, mothers had to be (1) 18 years or older, (2) able to speak English, (3) seen within a 24-hour window of rendering the decision of interest, and (4) willing to be audiotaped. Once eligibility was determined, the study was explained in detail and written informed consent was obtained. Interviews were conducted in the mother's hospital room at that time or later the same day. Family members (eg, newborn's father) who were present were allowed to stay with the participant's permission and were made aware the interview would be audiotaped.

### Ethical considerations

Approval to conduct the study was obtained from the appropriate university institutional review board. Mothers were free to stop the interview at any point or decline to answer particular interview questions. No names were included on audiotapes or transcripts to ensure confidentiality of the participants. No incentives were offered for participating in the interviews.

### Data collection

#### *Observations*

Passive participant observation was used to collect data on (1) the physical setting in which the consent discussion occurred, (2) informational materials provided, (3) individuals present in the room during the consent and interviews, (4) activities and interactions, and (5) nonverbal behaviors to emphasize the importance of contextual factors of the postpartum period during the BioTrust consent process.

#### *Semistructured interviews*

An interview guide was developed (see Table 1) using information in the BioTrust brochure,[24] essential biobanking informed consent topics,[14] and concepts in the MMIC.[12] Content validity was established by team members with expertise in informed consent (A.R.T.) and maternity care (ie, certified nurse midwife [L.K.L.]). The interview guide was pilot tested with 5 mothers. Additional questions were asked at the completion of the 5 interviews to elicit feedback about the interview process and to assess whether anything asked was unclear. As no suggestions for change were provided, these 5 interviews were included in the final sample.

Following the consent process, mothers were interviewed to examine their knowledge of the rDBS and biobanking research, experience with the consent process, and personal values. Knowledge was assessed by asking each participant to describe her understanding of the blood spots, NBS, the BioTrust, and biobanking. Next, each mother was asked to describe the informed consent process that had just occurred and to reflect

**Table 1. Interview questions, probes, and categories**

| Interview questions | Probes | Category |
|---|---|---|
| First, please describe to me what you know about the blood spots from the newborn screening test? | What do you understand about the blood spots from the newborn screening test? | Newborn screening knowledge |
| Please tell me what you know about the Michigan BioTrust. | | BioTrust knowledge |
| Next, please describe how you were asked for permission to donate the leftover blood spots to the BioTrust as you experienced it. | Who asked for your permission? What did he or she tell you? What happened? | Informed consent |
| What was your decision about the donating your baby's blood spots to the biobank? | Did you agree or not agree to donate your baby's blood spot to the biobank? | Donation decision[a] |
| What kinds of thoughts, questions, or concerns were in your mind as you made your decision? | | Values/attitudes perceived risks |
| Do you think your questions were answered? How was this done? | By whom or by what information? | Informed consent |
| Do you think you were you able to get the information that you needed to make the decision? | | Informed consent |
| Is there any additional information that would have been helpful to you in making this decision? | | Informed consent |
| If you had more time, would you be willing to find more information? | | Informed consent |
| What did you find helpful or unhelpful to you to make the decision to donate your baby's blood spot to the Michigan BioTrust? | | Informed consent |
| Please tell me about how you chose (yes/no)? | What was important to you in making the decision? | Values/attitudes |
| What personal experiences, values, opinions, or religious beliefs of yours do you think may have influenced your decision? | How did _____ affect your decision? Can you give me an example? | Values/attitudes |
| What have you heard about biobanking? | Can you please describe biobanking in your own words? | Biobanking knowledge |
| What is the purpose of the Michigan BioTrust? | | Knowledge informed consent |
| Next, please describe your expectations about medical research involving your child's genetic information/blood spots. | | Attitudes/values |
| Do you have any concerns about medical research involving your child's genetic information/blood spots? If yes, please explain. | | Perceived risks |
| Are there things you would want or would not want the blood spots used for? | Like what? Can you please give me an example? | Attitudes/values |
| On a scale of 1-5 (rating described), how would you rate your confidence in your decision? | | Confidence |
| If you were to change your mind about donating, what would you have to do? | | Informed consent |
| Please complete the following sentence: For me, personally, donating (or not donating) my newborn's blood spots for research is_(fill in the blank)____.[b] | | Attitudes |
| Anything you would like to add about your experience and decision regarding the BioTrust? | | Summation |

[a] 19 of 20 decisions were observed as they were made.
[b] Question adapted from Marteau et al.[12]

on questions or concerns she may have had during the decision-making process. Then, each mother was asked to repeat her decision and describe why she agreed or declined to donate her newborn's blood spots for research. Finally, each mother was asked to describe any personal experiences or personal or religious values she thought may have influenced her decision.

At the end of each interview, each mother was given an opportunity to provide any additional descriptions of her experience. Demographic data including age, education, race, religion, insurance status, and parity were also collected. After confirmation with the mother that she had no additional information to share, the interview was considered complete. The observations and interviews were conducted over 4 days during October to November 2016.

### Data analysis

Data were analyzed using qualitative content analysis; steps included (1) preparation, (2) organizing and coding the data, and (3) reporting the results.[25] Preparation included verbatim transcription of the audiotaped interviews (E.R.E.). This involved scrutinizing the data, accomplished by listening to each interview multiple times as part of the transcription process, and then by reading, rereading, and abstracting the interview transcripts (E.R.E. and C.M.A-E.). Next, data were organized using codes developed on the basis of categories in the MMIC framework and interview questions (eg, knowledge, attitudes, and decisions), key words, and phrases. Narrative data were extracted from the transcripts, organized in tables, reviewed, and iteratively compared. Data matrices were then created to compare and contrast responses and demographics of mothers who decided to donate or not donate their newborn's rDBS. The unit of analysis was the collective experiences of the 20 mothers who participated in the qualitative interviews.

To classify decisions as informed or uninformed, responses to knowledge questions were classified as either good (+) or poor (−) by 2 coders (E.R.E. and C.M.A-E.). Responses consistent with factual materials (eg, per the BioTrust brochure[24]) were classified as good knowledge, whereas inconsistent responses or statements such as "I do not know" were classified as poor knowledge. Similarly, attitudes were classified into positive and negative categories. Favorable, optimistic thoughts or feelings toward blood spot research were characterized as positive attitudes, whereas negative attitudes were marked by suspicious thoughts or feelings toward such research. Using the MMIC definition of an informed choice, there were only 2 possible combinations of knowledge, attitude, and donation decisions that would constitute an informed decision.[12] Option 1 was when a mother had (*a*) good knowledge about the BioTrust and biobanking, (*b*) a positive attitude toward rDBS research, and (*c*) agreed to donate her newborn's rDBS. The other option was when a mother had (*a*) good knowledge about the BioTrust and biobanking, (*b*) a negative attitude toward rDBS research, and (*c*) declined to donate her newborn's rDBS (see the Figure). Choices based on poor knowledge and/or attitudes incongruent with decision making were classified as uninformed choices per the MMIC framework.[12]

Trustworthiness of the data was reinforced by the use of audiotape and subsequent verbatim transcription of the interviews. Participants' views were confirmed through informal member checking and probes used during the interviews to clarify statements.[26] The sample size was deemed adequate after the 14th interview as determined by data saturation, the point when new information stops occurring and established responses continue to repeat.[26,27] Interrater reliability was established using the approach of Miles and Huberman[28] (the number of agreements divided by the total number of agreements and disagreements). Categorization of participants' responses (ie, good or poor knowledge, positive or negative attitudes, level of perceived risk) was iteratively discussed, classified, and revised as needed between 2 coders (E.R.E. and C.M.A-E.). Two evaluations of biobanking knowledge were changed from good to poor. Discordance was reconciled by further discussion and 100% consensus was reached.

## RESULTS

### Observations

The BioTrust consent process was observed 29 times and was estimated to be, on average, 5 minutes in length. Mothers who had given birth the previous day were identified from a daily census and approached regarding NBS education and potential rDBS donation. The same consenter, an unlicensed member of the ancillary staff, was observed for all consent interactions. The consenter arranged her visits with mothers according to time of delivery and approached mothers before the heel stick procedure for NBS occurred. While the consenter strived to give each mother as much time to rest after birth as possible time constraints existed, as NBS must be conducted after the newborn is 24 hours old but before leaving the hospital.

The consenter respectfully introduced herself to the mother by name and job title and explained she was there to talk about NBS. Next, the consenter asked each mother whether she was familiar with the newborn heel stick and described the process. At this institution, mothers were given a folder of information at

admission, including brochures on NBS[29] and the BioTrust,[24] and these folders were observed to be present in the mother's room during the consent process. The consenter verbally referenced the brochures stating, "There's a pamphlet in your folder . . . ." However, a detailed review of those materials was not observed, nor were informational materials used that explained potential controversial types of research (ie, moral risks). The consenter explained that 6 blood spots would be collected to screen for more than 50 metabolic diseases, often briefly describing examples (eg, phenylketonuria and cystic fibrosis). Next, the consenter described the difference between screening and research by stating: "The state also wants me to ask if they can use the leftover blood for anonymous medical research. The screening is required, but you can say yes or no to the research." The manner used to present the information and the language used were the same at each encounter. Before checking a yes or no box to indicate a participation choice, each mother looked at the BioTrust consent form on the back of the NBS blood spot card that summarizes key information.[30] However, the extent to which mothers actually read or understood the information is unknown. Mothers (and fathers) tended not to ask questions during the BioTrust consent process. Eye contact and puzzled facial expressions were observed between mothers and fathers before responding to the consent question. If silence was prolonged, the consenter prompted the mother by stating, "The blood spots either go to the biobank for research or sit with the state. It's up to you." Mothers (or fathers) verbally expressed a choice and then one signed the blood spot card accordingly. During one observation, parents contradicted each other's decision to donate: the mother stated she wanted to agree, and the father stated he wanted to decline donation. Subsequently, the mother declined. Family members were frequently observed in the room with the mother (eg, fathers were present in 15/20 [75%] interviews). Mothers identified others present at the time of the BioTrust consent and/or the interviews as an aunt, a sister-in-law, and grandparents.

## Interviews

Twenty mothers (20/29; 69%) participated in the semistructured interviews, and 9 mothers declined (9/29; 31%). Interviews lasted 6 to 20 minutes (median = 8 minutes). The median age of participants was 32 years (range, 23-42 years); most were multiparous ($n$ = 15), with this birth most often being their second child ($n$ = 10). Three-fourths ($n$ = 15) had at least some college or a college degree. Sixty-three percent of the mothers identified a religious affiliation and indicated the practice of their faith was important ($n$ = 12/19; 63%). Of those mothers who identified a religion, the importance of the practice of their faith was rated highly (average 8.75 on a 10-point scale).[31] Characteristics of the participants are presented in Table 2.

### *Knowledge*

Fourteen mothers (70%) were able to correctly describe knowledge of the NBS by stating: ". . . screening for these different diseases and they will tell us if our child has them and what we need to do to treat them to prevent certain symptoms" and ". . . check[ing] for different diseases or illnesses that babies could have." Conversely, when asked to describe the Michigan BioTrust, most mothers (16/20; 80%) stated, "I don't know anything about it" or "nothing" about it. Similar responses were noted when asked to describe biobanking. Most mothers ($n$ = 16/20; 80%) indicated they did not have any knowledge of it, stating, "Biobanking? I don't know" and "Sorry, I don't know."

Five of the mothers who declined to donate the rDBS for research described a "lack of information around the process" and clearly stated, "I just really didn't know anything . . . about the research part of it so that's why my answer was no." Mothers described "the inability to get clear information" and their unwillingness to "put my child out there" because "I just don't know a lot of information." One mother perceived that donation options were not "presented equally" and described the BioTrust brochure as "definitely geared toward you saying yes."

In addition, 4 types of misunderstandings emerged from the narrative data, involving 11 of the mothers. One mother who declined donation misunderstood the procedure and said, "I just don't want him to be more uncomfortable," believing donation would require the newborn to have a second heel stick. Two other mothers agreed to donate because they perceived that "it's [the university hospital] asking me" and felt "[the university hospital] does a lot of good research . . . I am happy to participate." Four other mothers who agreed to donate stated since ". . . it's totally anonymous," and one said, "If it wasn't anonymous, I probably wouldn't do it . . . ." Five mothers indicated a "nurse" entered the room to ask for consent.

### *Attitudes*

All of the mothers who agreed to donate rDBS ($n$ = 14) had attitudes about the research classified as positive. The 6 mothers who declined to donate rDBS had attitudes classified as negative. No choice was inconsistent with the stated attitudes about the research.

Mothers who agreed to donate their newborn's blood spots ($n$ = 14; 70%) overwhelmingly described wanting to do "good" and to "help" others. One mother said

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**Table 2. Characteristics of interviewed mothers[a]**

| | | Donation decision | |
|---|---|---|---|
| | | Yes ($n = 14$), % | No ($n = 6$), % |
| Age, y | | | |
| Median | 32 | 34 | 24 |
| Range | 23-42 | 25-42 | 23-29 |
| | ***n* (%)** | ***n* (%)** | ***n* (%)** |
| Race | | | |
| Asian | 1 (5) | 0 (0) | 1 (17) |
| Black or African American | 2 (10) | 0 (0) | 2 (33) |
| White or Caucasian | 12 (60) | 11 (79) | 1 (17) |
| Other (Arabic, mixed-race, other) | 4 (20) | 3 (21) | 1 (17) |
| Missing[b] | 1 (5) | 0 (0) | 1 (17) |
| Religion | | | |
| Christian | 6 (30) | 3 (21) | 3 (50) |
| Muslim | 5 (25) | 3 (21) | 2 (33) |
| None | 7 (35) | 7 (50) | 0 (0) |
| Unitarian | 1 (5) | 1 (7) | 0 (0) |
| Missing[b] | 1 (5) | 0 (0) | 1 (17) |
| Highest level of education completed | | | |
| High school | 4 (20) | 1 (7) | 3 (50) |
| Some college | 6 (30) | 5 (36) | 1 (17) |
| Bachelor's degree | 4 (20) | 4 (29) | 0 (0) |
| Master's degree | 4 (20) | 3 (21) | 1 (17) |
| Professional degree (PhD, MD) | 1 (5) | 1 (7) | 0 (0) |
| Missing[b] | 1 (5) | 0 (0) | 1 (17) |
| Insurance coverage | | | |
| Public (Medicaid) | 8 (40) | 5 (36) | 3 (50) |
| Private (employer/ self-insured) | 10 (50) | 9 (64) | 1 (17) |
| Both | 1 (5) | 0 (0) | 1 (17) |
| Missing[b] | 1 (5) | 0 (0) | 1 (17) |
| No. of live births (including this baby) | | | |
| 1 | 4 (20) | 3 (21) | 1 (17) |
| 2 | 10 (50) | 7 (50) | 3 (50) |
| ≥3 | 5 (25) | 4 (29) | 1 (17) |
| Missing[b] | 1 (5) | 0 (0) | 1 (17) |
| Confidence in decision—average (1, uncertain; 5, very confident) | | | |
| Overall | 4.4 | 4.5 | 4.2 |

[a] % Columns may not total 100% due to rounding.
[b] Missing data = 1 mother declined to answer demographic questions.

donating blood spots was about "helping, helping others, finding cure, helping finding cure, hopefully." Mothers described blood spot donation as a way "... to be socially responsible..." and "...advance medical care...." Mothers frequently ($n = 12$; 60%) expressed the perception of research as a benevolent act. One mother said, "... research is good. Let's do that!" and 2 other mothers stated they were "always pro-research."

### *Perceived risk*

Three mothers who agreed to donate rDBS perceived no risks with the research. One participant stated, "They're not ... to harm my child, so, why not [participate]!" Nine others who agreed to donate perceived "little" or "small" risks, and one of these mothers expressed that the research was "low enough risk that I'm not too worried about it." The perception of low risk was often linked to the fact the blood spots were "leftover" and there would not be "an extra prick" for the newborn.

However, mothers who declined to donate perceived more risk and stated, "... it's private information. I don't want it to go out in public," and expressed concerns the blood spots would be used for "commercial reasons




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... for profit." Additional concerns included "any negative research" and "uncertainty about how it's going to be used."

Six mothers (30%) mentioned religious, spiritual, or moral issues as they described their donation decisions. Two mothers who agreed to donate associated "trying to help each other" with their religious beliefs. They stated, "[My congregation] really believe in the inner connectedness of all livings beings" and "I hope to God they find cures for illnesses." Two other mothers agreed to donate despite expressing moral concerns. They said: "Just don't clone them" or use the blood spots for "anything like immoral, like ... abortion." One mother who declined to donate stated, "... I believe in certain things like being Christian for one, and in Christ and all that," and she feared the blood spots may be used for "witchcraft." Another mother denied that "visions" (ie, religious or spiritual entities) led her to say no but stated she declined on the basis of her lack of knowledge.

### *Mothers' descriptions of consent process*

The majority of mothers ($n = 12/20$; 60%) were able to describe the difference between NBS and the request to use rDBS for research. One mother stated:

> She came ... in and ... described ... the state requires six blood spots and they do some testing for children ... and then ... she asked ... if we would be willing to ... use the leftover blood spots for research.

However, 8 mothers were unable to describe the difference clearly. One mother stated, "She just really just asked me if I ... want to it get a researched [*sic*] and I said yes, but I don't want those remaining blood kept."

Four mothers characterized the consent process as "straightforward" or "no big deal" and as an "easy decision." Two of these mothers reported "details" were not provided, nor were they always perceived as necessary. One mother stated, "... I think she didn't specify more details just because I didn't ask for them...."

Two mothers stated the speed at which the decision was made was "... like a one second decision!" and "... I made it on the fly!" A third mother stated, "I didn't think twice of it."

Two mothers specifically reported the brief explanation provided by the consenter to be "helpful" in making the decision and that the consenter "kind of went over it a little bit with us." Two other mothers stated they appreciated "having a choice" about donation (one said yes and one said no to donation), and 3 mothers explicitly denied feeling any pressure imposed by the consenter to influence their decisions. One said it was "very low pressure ... like it was okay either way." Another one stated she felt "no pressure at all," and the third mother said "it felt normal." However, another mother described that she did not find the process helpful stating: "... how can we give informed consent ... [a] couple of hours after a birth, when they've [*sic*] had all kind of narcotics and drugs, and trauma? And there is somebody in the room every half hour...."

When asked, "If you were to change your mind about donating what would you have to do?" Four mothers were able to described the process to withdraw from the BioTrust stating they would "[use] the Internet," "read the pamphlet," or "contact the state." Eight other mothers described it as "telling the lady" or "telling you guys," whereas others stated they did not know ($n = 5$) or did not understand the question ($n = 3$).

### *Demographics and decisions*

A total of 14 mothers agreed to donate their newborn's blood spots to the BioTrust, and 6 declined. Mothers who self-identified their race as white tended to agree to donate, whereas mothers who self-identified their race as nonwhite were split in their decisions (see Table 2). In addition, mothers who declined to donate tended to be younger in age (in their 20s) than mothers who agreed to donate rDBS, who were mostly in their 30s or older than 40 years. Twelve mothers ($n = 12/19$; 63% of those who answered demographic questions) reported a religious affiliation (ie, Christian, Muslim, or Unitarian); 5 of those 12 (42%) mothers declined to donate rDBS, whereas all 7 mothers who indicated no religious affiliation agreed to donate their newborn's rDBS. Education, insurance status, and number of births did not seem to be exclusively associated with any particular donation decisions (see Table 2).

On the basis of the MMIC[12] classifications, 4 mothers (20%) made an informed choice: a choice congruent with both (*a*) possessing good knowledge and (*b*) consistent with personal attitudes toward blood spot research. Sixteen mothers (80%) lacked adequate knowledge to make an informed choice. Informed choices included 3 mothers who agreed to donate and 1 mother who declined. Only 3 of the 4 mothers who made an informed choice were willing to answer demographic questions. All 3 of these mothers were in their 30s, had at least some college education, and identified a religious affiliation. Two had private insurance and one had public insurance (ie, Medicaid). Two mothers were multiparous and one a first-time mother; fathers were present in 2 out of 4 instances of informed choice. All mothers indicated they were fairly confident with their decisions (see Table 2).

## DISCUSSION

Observation of the BioTrust consent process indicated that information provided to mothers lacked depth, which may have contributed to lack of adequate knowledge and frequent misunderstandings. This finding is consistent with a recent focus group study that included 69 participants from 3 states and reported that individuals frequently found information on the MDHHS blood spot card consent form confusing.[32] Observations also confirmed previous reports[33,34] that the postpartum environment is not conducive to education about NBS and rDBS research, as mothers described being sleep-deprived, fatigued, under the effect of medication or in pain, and were observed to be preoccupied with their new baby. While the consenter's approach was professional and friendly, it was also routine, brief, and observed to elicit only a yes or no response. Routinization of consent for other postpartum decisions (eg, newborn care, pain medication, breastfeeding, and male circumcision) has been noted to overlook patients' values and the emotional consequences of the decisions and thereby impede meaningful informed consent.[35,36] Shared decision-making[37] in which patients' values and preferences are openly discussed and clarified might be a better approach to aid informed choices. Extended discussion with a person knowledgeable about details of the research is still the most efficacious intervention to aid understanding of consent information.[38,39]

Semistructured interviews revealed that the majority of the mothers ($n = 16$; 80%) made the decision without adequate knowledge of the BioTrust or biobanking and thus these decisions failed to reach the threshold of an informed choice.[12] Findings were consistent with the current literature, which indicates that many participants lack understanding of key elements of informed consent for biobanking[40] and that low knowledge scores contribute to other uninformed decisions including those involving prenatal testing[12,20,21] and declining to vaccinate children.[41]

The 6 mothers who declined to donate perceived higher risks to personal values (eg, privacy and research uses). However, even 2 mothers who agreed to donate expressed moral caveats on research involving abortion and cloning, indicating perceptions of moral risk. Indeed, rDBS have been used to study birth defects and develop new techniques for prenatal genetic diagnosis.[42,43] Research from Canada and the United Kingdom demonstrated that advances in prenatal genetic testing have contributed to an increase in abortions due to the presence of fetal anomalies.[44,45] Moreover, one of these mothers held the misperception that the request for rDBS was emanating from the hospital, a trusted institution in the community, although the request was actually from the MDHHS. Misperceptions about anonymity, the consenter's credentials, and the entity conducting the research were common. Thus, it is crucial to clarify specific points including that blood spots are coded, but not anonymous, the consenter's credentials (eg, registered nurses vs unlicensed personnel), which have been shown to influence biobanking decision making,[40,46] and that the request for rDBS is coming from the state department of health, not a trusted hospital or consenter. Parents need accurate information on which to base their donation decisions, and understanding should be verified. Observations also indicated that fathers wanted to be more involved in rDBS education and decision making.

### Limitations

The study sample was a small, convenience sample of mothers derived from a single data collection site, where only one consenter was observed, which may limit the generalizability of results. The MMIC[12] attributes an informed choice to only 3 categories: knowledge, attitudes, and participation. An informed choice may be more complex and involve deliberation,[21] which is not captured in the MMIC. Finally, despite efforts by the PI to be as unobtrusive during the consent process, the potential for a Hawthorne effect cannot be ruled out. The consenter knew she was being observed, which may have influenced her behavior.[26] Nevertheless, this study provided valuable data on the BioTrust consent process and mothers' decision-making process.

### Clinical Implications

Based on findings from this study, 3 recommendations are put forth: (1) education about NBS and rDBS research should begin at prenatal visits, outside of the postpartum environment; (2) information provided to parents about research on rDBS must be accurate, comprehensive, and include ethical implications of biobanking; and (3) consenters should be required to complete training on communication skills, ethical issues involved in rDBS research, and shared decision-making techniques, in addition to formal human subjects' training.[47]

## CONCLUSION

This study examined the consent process and decisions of mothers asked to donate their newborn's rDBS for research purposes to the Michigan BioTrust. While most mothers agreed to donate the blood spots, many decisions were based on inadequate knowledge and misunderstandings. Therefore, policy and procedure changes are needed to restructure the consent process to promote informed choices. While individuals' level of

biobanking knowledge may be difficult to improve, the context, content, and delivery of the BioTrust consent process may be more amenable to change.

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**EMPLOYMENT**

**George Washington University Law School,** Washington, D.C.
1999-2010 Associate Professor of Law
2010-present Professor of Law
2018-present The John R. and Inge P. Stafford Faculty Research Professor
Courses: Torts, Genetics & Law, Law & Medicine, Reproductive Technologies

1997-99 **Greenwall Fellowship in Bioethics and Health Policy,** Washington, D.C./Baltimore, MD
Jointly administered by Georgetown University and Johns Hopkins University. Independent research in bioethics, law, and policy with a focus on genetics.

1998-99 **Georgetown University Law Center,** Washington, D.C.
Adjunct Professor of Law. Seminar: Genetics and the Law

**University of Michigan Law School,** Ann Arbor, MI
1996-1997 Visiting Faculty. Courses: Torts, Genetics and the Law, Medical Decision Making
1995-1996 Faculty Fellow. Seminar: Genetics and the Law

1994-1995 **Judge John M. Walker, Jr.,** U.S. Court of Appeals for the Second Circuit, New York, NY
Law Clerk. Researched, drafted, and edited opinions and bench memoranda.

Summer 1994 **Honigman, Miller, Schwartz & Cohn,** Detroit, MI
Summer Associate. Worked on articles of incorporation for hospital clients, prepared memoranda on potential liability for hospitals, defenses for charges of tax evasion, etc.

Summer 1993 **Miller, Canfield, Paddock & Stone,** Detroit, MI
Summer Associate. Prepared memoranda on corporate veil piercing, CERCLA liability, copyright infringement, safe harbor provisions of Medicare Fraud and Abuse statute, etc.

Summer 1992 **Medical Center Attorneys Office, University of Michigan,** Ann Arbor, MI
Law Clerk. Prepared memoranda on issues including expert witness privileges, minors and consent, and implications of human genome project.

1989-1991 **Henry Ford Hospital,** Detroit, MI
Genetic Counselor. Counseled pediatric and obstetric patients about genetic testing and inheritance of genetic diseases. Newborn Screening Coordinator. Trained students.

Spring 1986 **Universität Zürich,** Zürich, Switzerland
Research Assistant. Involved in studies of mutagenic effects of various chemicals on rats and papers on neurological effects of AIDS virus.

**EDUCATION**

**University of Michigan Law School,** Ann Arbor, MI. **J.D., Magna Cum Laude**, 1994
Henry M. Bates Memorial Scholarship, highest Law School award – Executive Articles Editor, *Michigan Law Review*, Vol. 92 - Book Awards: Property; Writing and Advocacy; Law, Medicine, and Bioethics; and Health Care Reform

**University of Michigan,** Ann Arbor, MI. **M.S. Human Genetics,** 1987
Doctoral Candidate, Human Genetics, 1988 - National Institute of Health Training Grant - Arthur F. Thurnau Fellowship for Molecular Biology - Phi Kappa Phi Graduate Fellowship - Teaching Assistant for Writing for Science Majors, 1987

**Michigan State University,** East Lansing, MI. **B.A. High Honors, English,** 1985
Rhodes Scholar State Finalist - Phi Beta Kappa – The Outstanding Academic Achievement Award from the College of Arts and Letters - Ryder Scholarship for Overseas Study - Intern, Congressman Carr's 6th District Office, Summer 1984 - Invited to present paper at Ohio State University, Undergraduate Philosophy Conference, 1984

**PUBLICATIONS**

GENETICS: ETHICS, LAW AND POLICY (co-authored with Maxwell J. Mehlman & Mark A. Rothstein) (West Academic Publishing, forthcoming 2020)

*National Institute of Family and Life Advocates v. Becerra, 138 S. Ct. 2361 (2018), in* FEMINIST JUDGMENTS REWRITTEN HEALTH LAW OPINIONS (Seema Mohapatra & Lindsay Wiley eds., Cambridge University Press forthcoming 2020)

*Genetics and the Law, in* OXFORD HANDBOOK ON COMPARATIVE HEALTH LAW (co-authored with Max Mehlman & Mette Hartlev) (David Orentlicher & Tamara Hervey eds., Oxford University Press, forthcoming 2020)

*Legal Challenges in Genetics, Including Duty to Warn and Genetic Discrimination, in* GENETIC COUNSELING: CLINICAL PRACTICE AND ETHICAL CONSIDERATIONS (Laura Hercher et al., Cold Spring Harbor Laboratories Perspectives in Medicine, 2020)

*GINA at Ten Years: The Battle over "Genetic Information" Continues in the Courts*, 5 J.L. & BIOSCIENCE 495 (2019), https://doi.org/10.1093/jlb/lsz002

*The Tyranny of Choice: Reproductive Selection in the Future,* 5 J.L. & BIOSCIENCE 262 (2018), lsy014, https://doi.org/10.1093/jlb/lsy014

*The Limits of Empirical Data: How to Understand Survey Result with Respect to Gamete Donor Anonymity*, 3(2) J.L. & BIOSCIENCE 377 (2016)

*Book Review: The End of Sex and the Future of Human Reproduction,* 3(2) J.L. & BIOSCIENCE 436 (2016)

In vitro *Gametogenesis: Just Another Way to Have a Baby?*, 3(1) J. L. & BIOSCIENCES 87 (2016)

*The Problem of Liminal States, Line Drawing, and False Dichotomies*, 2 J. L. & BIOSCIENCES 1 (2015)

*Genomic Medicine: New Norms Regarding Genetic Information*, 15 HOUS. J. HEALTH L. & POL'Y 83 (2015)

*The First Amendment and Physician Speech in Reproductive Decision Making*, 43 J. L. MED. & ETHICS 22 (2015)

*Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening,* 15 MINNESOTA J. L. SCI. & TECH. 729 (2014)

*Interest Creep and The Politics of Constitutional Common Law*, 80 GEO. WASH. L. REV. ARGUENDO 29 (2014)

*How Big a Problem is Genetics Exceptionalism in Employment?*, HASTINGS CTR. REP. , Nov.-Dec. 2013, at 5

*The Politics of Information: Informed Consent in Abortion and End-of-Life Decision Making*, 39 AM. J. L. MED. 7 (2013)

*Review of* Am I My Genes? Confronting Fate and Family Secrets in the Age of Genetic Testing *by Robert Klitzman*, 12(10) AM. J. BIOETHICS 52 (2012)

*Bad Mothers or Struggling Mothers?*, 42 RUTGERS L. J. 695 (2012)

*From Sweaty Towels to Genetic Stats: Stalking Athletes for Their Genetic Information*, 6 RECENT PATENTS ON DNA & GENE SEQUENCES 189 (2012)

*All in the Family: A Modified Deontological Analysis of DNA Familial Searching*, 23 HARV. J. L. & TECH. 309 (2010)

*Giving in to Baby Markets*, *in* BABY MARKETS: MONEY AND THE NEW POLITICS OF CREATING FAMILIES (Michele Goodwin, ed. Cambridge Univ. Press, 2010)

*Giving in to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L. 169 (2009)

*The "Repugnance" Lens of* Gonzales v. Carhart *and Other Theories of Reproductive Rights: Evaluating Advanced Reproductive Technologies*, 76 GEO. WASH. L. REV. 1514 (2008)

*A Brave New World of Designer Babies?,* 22 BERK. TECH. L.J. 897 (2007)

*Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737 (2004)

Co-author of Ruth Faden et al., *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*,@ HASTINGS CTR. REP., July-Aug. 2003, at 2

Co-author of Liza Dawson et al., *Safety Issues in Cell-Based Intervention Trials*, 80 FERTILITY & STERILITY 1077 (2003)

*The Routinization of Prenatal Testing: Cause and Effect*, 28 AM. J. LAW. & MED. 233 (2002)

*The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79(3) WASHINGTON UNIVERSITY LAW QUARTERLY 669 (Oct. 2001)

*Genetic Testing and the Use of Information: Book Review*, 41 JURIMETRICS 261 (2001)
*Ambivalent Unanimity, in* LAW AT THE END OF LIFE (Univ. Mich. Press, 2000)

*Commentary: Ethical Issues in Genetic Testing*, 8 KENNEDY INSTITUTE OF BIOETHICS JOURNAL 161 (1998)

*Case Law in Genetics, in* MAPPING PUBLIC POLICY FOR GENETIC TECHNOLOGY: A LEGISLATOR=S RESOURCE GUIDE (1998)

*Challenges in Drafting Genetics Legislation, in* MAPPING PUBLIC POLICY FOR GENETIC TECHNOLOGY: A LEGISLATORS= RESOURCE GUIDE (1998) with L. Gostin and R. Quigley

*Sex Selection, Nondirectiveness, and Equality*, 3 U. CHICAGO L. SCH. ROUNDTABLE 473 (1996)

*Whose Genes Are These Anyway?*, 91 MICHIGAN LAW REVIEW 1854 (1993)

*Isolation and Characterization of the Rat Plasminogen Activator Inhibitor-1 Gene*, 265 JOURNAL OF BIOLOGICAL CHEMISTRY 2078 (1990)

*Dieldrin Inhibition of Gap Junctional Intercellular Communication in Rat Glial Cells as Measured by the Fluorescent Photobleaching and Scrape Loading/Dye Transfer Assay*, 9 FUNDAMENTAL AND APPLIED TOXICOLOGY 785 (1987)

**TALKS**

*Should the Government Use DNA Databases to Solve Crimes*, 2020 ILLUMINA GLOBAL SALES MEETING, Hilton San Diego Bayfront, San Diego, CA, Jan. 15, 2020

*Balancing the Risks of Genetic Genealogy Forensics*, HEARINGS ON FAMILIAL DNA AND CRIMINAL INVESTIGATIONS, Judiciary Committee, Maryland House of Delegates, Cambridge MD, Nov. 7, 2019

*Legal Issues in Genetics,* GENETIC COUNSELING LEADERSHIP SEMINAR, Department of Human Genetics, University of Pittsburgh, Pittsburg, PA, Oct. 25, 2019

*Abortion Exceptionalism in* NIFLA v. Becerra, 2019 HEALTH LAW PROFESSORS CONFERENCE, ASLME & Loyola Law School, Chicago, IL, June 5, 2019

*Rewrite of* National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018),* BABY MARKETS ROUNDTABLE, The George Washington University, Washington, D.C., June 2, 2019

*Disclosure Obligations in Oncology Research and Clinical Care: Who Must Be Told Me What and When?*, RUTH BRUFSKY MEDICAL ETHICS LECTURE, Dana-Farber Cancer Institute, Boston MA, Oct. 29, 2018

*Reproductive Testing for Breast/Ovarian Cancer Risk,* BABY MARKETS ROUNDTABLE, UC Hastings Law School, San Francisco, CA, May 4, 2018

*Reproductive Autonomy and BRCA Testing: Ethics and the Law*, DANA-FARBER CANCER INSTITUTE GENETIC COUNSELING CONFERENCE (Keynote Speaker), Boston, MA, Apr. 28, 2018

*GINA's Ten-Year Checkup,* GINA at 10 Years, 2018 AALS ANNUAL MEETING, San Diego, CA, Jan. 5, 2018

*Genetics and Genomics: The Regulation of Insurance*, 14TH ANNUAL GLOBAL AGING CONFERENCE, Zurich, Switzerland, Nov. 3, 2017

*The Tyranny of Choice,* ETHICS AND REGULATION OF IN VITRO GAMETOGENESIS, King's College, London, England, Sept. 14, 2017

*The State of Abortion Law*, GOALS AND PRACTICES FOR NEXT-GENERATION PRENATAL TESTING, The Hastings Center, Garrison, NY, May 16, 2017

*Comment on Debra Wilson, "Enforcing Criminal Prohibitions on Surrogacy Arrangements,"* BABY MARKETS ROUNDTABLE, University of Texas, Austin, TX, May 9, 2017

*The Tyranny of Choice,* BABY MARKETS ROUNDTABLE, University of Texas, Austin, TX, May 8, 2017

*The Tyranny of Choice,* BIO LAWLAPALOOZA 2017, Stanford Law School, Palo Alto, CA, April 21, 2017

*The Impact of Routinization and of the Law on Patient Choice*, GOALS AND PRACTICES FOR NEXT GENERATION PRENATAL TESTING, The Hastings Center, Garrison, NY, June 10, 2016

*The Future of Reproductive Rights and* Whole Women's Health, THE LAW AND ABORTION ACCESS, The George Washington University Law School, Washington, D.C., March 10, 2016

*The Offer of Prenatal Testing: Informed Choice and the Law*, NHGRI GENETIC COUNSELING SEMINAR, The National Institutes of Health, Feb 26, 2016

King v. Burwell: *The Third Supreme Court Visit with the Affordable Care Act*, CURRENT CONSTITUTIONAL CONTROVERSIES, The George Washington University Law School, Washington, D.C., August, 13, 2015

*Legal Protections of Genomic Information, Squaring Ethics, Privacy, Law and Policy*, 9TH CONGRESS OF THE INTERNATIONAL SOCIETY OF NUTRIGENETICS AND NUTRIGENOMICS, University of North Carolina, Raleigh, N.C., May 18, 2015

*Navigating Informed Consent for Abortion Patients*, GW LAW STUDENTS FOR REPRODUCTIVE JUSTICE PRESENTATION, The George Washington University, Washington, D.C. Mar. 24, 2015

*Genomic Medicine: New Norms Regarding Genetic Information*, WORKSHOP ON AMERICA'S FUTURE HEALTH CARE SYSTEM: IMPLICATIONS FOR HEALTH LAW, POLICY, AND ETHICS, University of Houston Law Center, Houston, TX, Oct. 17, 2014

*Personalized Medicine and Genetic Privacy*, INTERNATIONAL PRIVACY SUMMIT, Georgetown University Law Center, Washington, D.C., June 5, 2014

*The First Amendment and Professional Speech: Informed Consent and Reproductive Decision Making*, CLASHING RIGHTS: FREE SPEECH AND REPRODUCTIVE AUTONOMY, Northeastern University School of Law, Boston, MA, April 25, 2014

Moderator, THE EMPLOYER MANDATE, RELIGIOUS LIBERTY AND WOMEN'S HEALTH: A DEBATE OVER *SEBELIUS V. HOBBY LOBBY STORES, INC.*, The George Washington University Law School, Washington, D.C. Feb. 18, 2014

*AMP v. Myriad: The Constitution and Technology,* CURRENT CONSTITUTIONAL CONTROVERSIES, The George Washington University Law School, Washington, D.C., Aug. 15, 2013

*DNA Art and Genetic Privacy*, STRANGER VISIONS: THE DNA YOU LEAVE BEHIND, Woodrow Wilson International Center for Scholars, Washington D.C., June 3, 2013

*The New Challenges of Consent in Genetics and Genomics,* THE 3RD NATIONAL CONFERENCE, GENETICS, ETHICS AND THE LAW, University of Virginia, Charlottesville, VA, May 22, 2013

*What Makes a Parent?* FAMILY BUILDING WITH DONOR GAMETES: NEW FAMILIES, NEW ISSUES AND INTERNATIONAL PERSPECTIVES, Georgetown Law, Washington, D.C., April 17, 2013

*Duty to Warn in the Context of Cardiovascular Genetics*?, NATIONAL SOCIETY OF GENETIC COUNSELORS, PRE-CONFERENCE SYMPOSIUM, UNIVERSAL GENETIC COUNSELING ISSUES VIEWED THROUGH A CARDIOVASCULAR LENS, Oct. 24, 2012

*How Technology is Changing Views of Genomic Privacy*, Testimony before the Presidential Commission For the Study of Bioethical Issues, Washington, D.C., Aug. 1, 2012

*Patients' Rights: Consent and Confidentiality*, GENETICS ETHICS AND THE LAW, University of Virginia, Charlottesville, VA, June 1, 2011

*Balancing Privacy and Innovation in Pharmacogenomics,* Innovations in Pharmacogenomics, BIOLAW/PRIVACY PANEL ON PHARMACOGENOMICS, AALS ANNUAL MEETING, Washington, D.C., Jan 6, 2012

*Familial Searches: Privacy and Other Issues*, 21ST INTERNATIONAL SYMPOSIUM ON HUMAN IDENTIFICATION, San Antonio, TX, Oct. 14, 2010

*Patients' Rights: Consent and Confidentiality*, THE THIRD ANNUAL VIRGINIA IRB CONSORTIUM, GENETICS, GWAS, GINA; "G" HOW DO WE KEEP UP?, University of Virginia Medical School, Sept. 29, 2009

*Legal and Ethical Challenges of Genetic Testing and Screening: Newborn Screening and Prenatal Testing,* GENETICS, ETHICS AND THE LAW, University of Virginia Law School, May 30, 2009

*Patients' Rights: Consent and Confidentiality,* GENETICS, ETHICS AND THE LAW, University of Virginia Law School, May 29, 2009

Comments on *Patenting People – Human Embryos, Genes, Physiology, and Thought as Intellectual Property,* BABY SELLING ROUNDTABLE, George Washington University Law School, April 17, 2009

Moderator, REPRODUCTIVE RIGHTS AND RELIGIOUS FREEDOM/EXPRESSION, GW Chapter of Law Students for Reproductive Justice, March 18, 2009

*Genetic Information Nondiscrimination Act of 2008: "GINA,"* PREPARING FOR NEW GENETIC DATA MANAGEMENT REQUIREMENTS, Online Audio Seminar sponsored by Health Information Privacy/Security Alert, July 30, 2008

*DNA Databases and Familial Searching*, FAMILIAL SEARCHING AND GENETIC PRIVACY SYMPOSIUM, Federal Bureau of Investigation, Arlington, VA, March 18, 2008

*Discussion of* Gonzales v. Carhart, PANEL ON PARTIAL BIRTH ABORTION, GW Law Chapter of Law Students for Reproductive Justice, Washington, DC, Nov. 7, 2007

*Evaluating Advanced Reproductive Technologies Through the "Repugnance" Lens of* Gonzales v. Carhart *and Other Theories of Reproductive Rights*, CONFLICTING INTERESTS IN REPRODUCTIVE AUTONOMY AND THEIR IMPACT ON NEW TECHNOLOGIES, George Washington Law Review Symposium, Washington, DC., Nov. 2, 2007

*A Brave New World of Designer Babies?,* Howard University Law School, Washington, DC, April 17, 2007

*A Brave New World of Designer Babies?*, JHU/NHGRI Genetic Counseling Training Program, NIH, Rockville MD, Apr. 13, 2007

*The Prospects for a Private NeoEugenics*, GENETIC DISABILITY: DNA PROFILING OF EMBRYOS AND FETUSES, Boston University, Boston, MA, April 8, 2005

*Third Party Access to Health Information: Issues in Genetics*, National Committee on Vital and Health Statistics, Subcommittee on Privacy and Confidentiality, Washington, D.C., January 12, 2005

*Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, Health Law Teachers Conference, Wilmington, Delaware, June 7, 2003

*Genetic Privacy*, GENETICS POLICY AND LAW: A NATIONAL FORUM, National Conference of State Legislatures, Washington, D.C., October 5, 2001

*Genetics Legislation: Cause and Effect*, THE BUSINESS OF MEDICINE, The Health Law Teachers 25th Anniversary Conference, Boston, MA, June 1, 2001

*Property or Privacy: How Should We Protect Medical Privacy?*, Greenwall Fellowship Program, Washington, D.C., May 8, 2001

*Property Rights and Reproductive Technologies*, National Association of Women Judges Seminar, Washington, D.C., March 24, 2000

*The Ethics and Legal Issues of Human Cloning*, National Association of Women Judges Seminar, Washington, D.C., March 24, 2000

*Challenges in Drafting Cloning Legislation*, NATIONAL CONFERENCE OF STATE LEGISLATURES 25TH ANNUAL MEETING, May 27, 1999

*Changing Landscapes: Evolving Decision Making Approaches in Genetics*, GENETIC TESTING, American Society for Bioethics and Humanities Annual Meeting, Houston, TX, Nov. 20, 1998

*The Legal Aspects of Genetic Testing*, CANCER GENETICS FOR THE ONCOLOGY PROFESSIONAL: CURRENT APPLICATIONS & THERAPEUTIC APPROACHES, New York, NY, Sept. 24, 1998

*Setting Public Policy for Genetics*, GIANT STEPS IN GENETICS, Chesapeake College Performing Arts Center, Wye Mills, MD, Apr. 7, 1998

*Ambivalent Unanimity*, COURTING DEATH, Univ. of Michigan, Ann Arbor, MI, Nov. 14, 1997

*Legal and Ethical Issues in Newborn Screening for Hearing Loss*, CDC, Atlanta, GA, Oct. 21, 1997

*A Fresh Look at Nondirectiveness*, Plenary Speaker, 1996 National Society of Genetic Counselors Annual Education Conference, San Francisco, CA, Oct. 28, 1996

*Sex Selection and Nondirectiveness*, University of Chicago Law School Roundtable Symposium on Genetics and the Law, Chicago, IL, Jan 20, 1996

**PROFESSIONAL ACTIVITIES**

2016-present **Editorial Board, OBM Genetics**

2016-present **Working Group Member of ELSI-funded project, "Goals and Practices for Next-Generation Prenatal Testing"**
This project includes an international working group of leaders of major clinical societies, clinical researchers, social scientists, philosophers, lawyers, and patient representatives to explore the ethics, law, and policy issues surrounding next-generation prenatal testing.

2014- present **Ethics Consultant, The Sudden Death in the Young (SDY) Registry**
This initiative, funded by the Centers for Disease Control in partnership with the National Institutes of Health, will utilize child death review to collect comprehensive data from multiple sources about the circumstances and factors associated with SDY deaths to help public health officials, prevention groups, and policy makers better implement effective prevention strategies.

2008-present **Biotech/Medical Board, Ethics Board, and Legal Board for Lifeboat Foundation**
Lifeboat Foundation is a think tank that includes philosophers, economists, biologists, nanotechnologists, educators, policy experts, lawyers, ethicists, neuroscientists, physicists, etc. to help consider the risks and possible misuse of increasingly powerful technologies, like genetic engineering, nanotechnology, and robotics.

2000-2007 **External Advisory Board of NIH-Funded REVEAL Study**
REVEAL (Risk Evaluation and Education for Alzheimer's disease) is a large-scale research study to evaluate the factors that influence adult offspring of individuals with Alzheimer=s disease to undergo genetic testing for Alzheimer=s disease. The External Advisory Board monitors the study to ensure that it protects the interests of the participants of the study.

2001-2006 **Expert Panel of American College of Medical Genetics Newborn Screening Project**
HRSA-funded interdisciplinary project to outline a process of standardization of outcomes and guidelines for state newborn screening programs and to define responsibilities for collecting and evaluating outcome data.

2000-2006 **Non-Medical Institutional Review Board,** George Washington University Law School
Multidisciplinary committee that provides oversight for all non-clinical or non-medical research in the social sciences, including research into human behavior and psychology, education, political science, law and criminology, culture, and the arts.

2002-2003 **Working Group of Greenwall-Funded Grant: AEthics and Cell Engineering@**
Multidisciplinary group that examined the ethical, legal, and scientific issues regarding stem cell research with focus on the selection of source of stem cells as well as the selection of

stem cell lines from which human therapeutics will be developed. Publication of two articles.

2002-2003 **Core Group of NIH-Funded Grant: AGerm-Line Interventions and Human Research Ethics"**
The Core Group examined how policy provisions and ethical principles would bear on research proposals to alter the genome of a human embryo when the goal is to allow that embryo to develop into a child.

1999-2001 **National Conference of State Legislatures Blue Ribbon Panel**
Chaired the Blue Ribbon Panel on Human Genetics Technologies Committee on Privacy, which assisted the National Conference of State Legislatures= Legislative Task Force in developing a state policy framework for genetic technologies.

1999-2001 **Genetics Advisory Committee for NIH-Funded Grant: AGenetics Legislation@**
Wrote grant for the funding for the Genetics Legislation Project, which provided legislators and other policy-makers with objective, comprehensive, and scholarly information about genetics -- science, law, and ethics -- to help facilitate drafting of sound genetics-related legislation. Provided oversight for the project.

1997-98 **Michigan Commission on Genetic Privacy and Progress,** Lansing, MI
Appointed by Governor Engler to serve on one-year, eleven-member. The commission recommended model state statutory and administrative policies to protect the privacy of genetic information, prevent discrimination, and regulate uses of genetic information to safeguard the interests of the public.

1997-1998 **Genome Technology & Reproduction: Values and Public Policy,** Ann Arbor, MI
Consultant on project investigating community views of reproductive genetics. Researched legal and professional standards related to reproductive genetics and developed policy recommendations. Co-facilitator in session on privacy and confidentiality in the national dissemination conference.

**INTERESTS** Photography – Jewelry-Making - Soloist Ann Arbor Ballet Theater (1989-94) – Travel– Languages: Spanish (advanced), German (conversational) - Piano: Michigan State Finalist 1981

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 29

**Sonia M. Suter, *Did you Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 Minn. J.L. Sci. & Tech. 729 (2014)**

**Minnesota Journal of Law, Science & Technology**

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# Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening

Sonia M. Suter

# Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening

**Sonia M. Suter***

ABSTRACT

*Newborn screening (NBS) has long offered the possibility of identifying rare conditions, which can be lethal or debilitating if not detected and treated quickly in the newborn period. These screening programs, usually mandatory, have been well established in every state since the 1960s. In the last decade, the number of conditions screened for has risen exponentially to include more than fifty inborn errors of metabolism, blood disorders, genetic, or other conditions. Not surprisingly, newborn screening programs have been widely accepted for their potential to save the lives of countless children.*

*Despite their valuable public health benefits, however, old approaches to, and more recent expansions of, NBS raise important privacy and policy concerns. NBS samples are collected in most states without affirmative, or sometimes any, consent from parents. NBS programs now screen for an ever-broadening range of diseases—sometimes without careful assessment of the risks and benefits—including conditions for which there is no treatment. NBS samples are retained for long periods or indefinitely. And finally, few, if any, limits prevent potentially invasive uses of these samples by the government or third parties. Indeed, evidence suggests that a great deal of research is being conducted on these stored blood spots, the*

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* Professor of Law, The George Washington University Law School. I am grateful to Naomi Cahn, Hank Greely, Pilar Ossorio, Mark Rothstein, Gil Siegal, and the participants of the Legal Scholars Workshop of the Genetics, Ethics and the Law Conference at the University of Virginia for their very thoughtful comments and suggestions. Many thanks also to my library liaison, Nicholas Stark, and my research assistants, Jessica Arco, Josh Oyster, Rebecca Szucs, and Kristen Ward, for their efficiency, thoroughness, and resourcefulness.

*collection and storage of which many parents are simply unaware. Only a few lawsuits and legislatures have addressed the legality of these practices.*

*With recent expansions in the scope of NBS and increased interest in these samples for research, it is time to take a fresh look at this long-standing public-health system and to reexamine some of the underlying philosophies and practices associated with it. While NBS offers important public health benefits, it also threatens some of the civil liberties of the parents and children involved. This piece argues for the need to strike a careful balance between the public goods and private interests, and describes a methodology that allows these competing values to be recognized in policymaking. It concludes by suggesting ways to balance the important values of maximizing the well-being of newborns and promoting research, while also protecting autonomy and privacy as much as possible.*



## INTRODUCTION

If you ask parents whether their child should undergo genetic testing or participate in research, most would probably say, consistent with legal norms in most areas of medicine, "only with my consent!" Yet the majority of parents do not realize that in every state, a small blood sample is collected from newborns to test for inborn errors of metabolism (many of which are inherited).[1] Nor do they realize that, in many states,

1. *See* Taralyn Tan, *Newborns' DNA: Don't Deny Scientists This Useful Resource*, GENETIC ENGINEERING & BIOTECH. NEWS (Apr. 13, 2010), http://www.genengnews.com/gen-articles/newborns-dna-don-t-denyscientists-this-useful-resource/4377 ("[I]n most cases, parents are not aware that the blood sample from their child is being kept at all.").

the dried blood spots (DBS) are retained for long periods or indefinitely, with few, if any, limits on third-party access to and uses of these samples.[2] Indeed, evidence suggests that a great deal of research is being conducted on these stored blood spots by the state and other entities.[3] All of this, from collection to retention of samples, often comes without parents' affirmative, let alone informed, consent.[4]

The impetus for mandatory newborn screening (NBS) is the fact that rarely, but quite significantly, a child will be born with abnormal levels of enzymes, metabolites, or other chemicals, which can be lethal or debilitating if not detected and treated in time.[5] NBS offers the possibility of identifying some of these conditions before clinical symptoms manifest and "before developmental disabilities or death occurs."[6] These, usually mandatory, screening programs have been well established in every state since the 1960s, potentially saving the lives of countless children.[7] The scope of NBS programs has expanded dramatically in recent years, with most states screening for between twenty-seven[8] and over fifty inborn errors of

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2. *See* Lori Andrews, *Public Choices and Private Choices: Legal Regulation of Genetic Testing*, *in* JUSTICE AND THE HUMAN GENOME PROJECT 46, 55 (Timothy F. Murphy & Marc A. Lappé eds., 1994) (noting that genetic information can change lives, "precipitated by the release of genetic information to third parties—such as when insurers or employers make adverse decisions against people based on genetic information"); Tan, *supra* note 1 (discussing DNA warehousing and the indefinite retention of samples).

3. *See, e.g.*, Tan, *supra* note 1 ("[S]torage . . . allows geneticists and neonatology researchers access to an incredible genetic database. These blood spot samples can be utilized to develop new genetic tests, to learn more about existing genetic disorders, and to study factors such as the mother's health and in utero environment in relation to rare disorders.").

4. *Id.*

5. *See Newborn Screening, Pediatric Genetics*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/ncbddd/pediatricgenetics/newborn_screening.html (last updated May 13, 2013) (discussing the importance of newborn screening and the benefits derived from the process).

6. *See* Michael S. Watson et al., *Newborn Screening: Toward a Uniform Screening Panel and System*, 8 GENETICS MED. 1S, 1S (Supp. May 2006) ("States and territories mandate newborn screening of all infants born within their jurisdiction for certain disorders that may not otherwise be detected before developmental disability or death occurs.").

7. *Id.* (discussing the importance of the state-based newborn screening programs that began over forty years ago).

8. STEFAN TIMMERMANS & MARA BUCHBINDER, SAVING BABIES? THE CONSEQUENCES OF NEWBORN GENETIC SCREENING 59 (2013) ("By 2010, all states screened for 27 . . . conditions."); Wylie Burke et al., *Genetic Screening*,

metabolism.[9] Some of these conditions have been added to the list without careful assessment of the risks and benefits,[10] and some are identified and reported with no known effective treatment.[11]

Even so, NBS has been a well-accepted part of our public health system for nearly half a century.[12] Recently, a few lawsuits have challenged the consent requirements with respect to NBS and related research. In 2003, a couple claimed that Nebraska's efforts to compel the screening of their newborn violated their religious freedom and parental rights.[13] The Nebraska Supreme Court found no such violation.[14]

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33 EPIDEMIOLOGIC REVIEWS 148, 149 (2011) ("In the United States, most states screen for at least 29 conditions . . . ."); *see also* ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 66 (Lori B. Andrews et al. eds., 1994) [hereinafter AGR] ("Newborns are usually screened today for several inborn errors of metabolism . . . .").

9. *See* Louise Moody & Kubra Choudhry, *Parental Views on Informed Consent for Expanded Newborn Screening*, 16 HEALTH EXPECTATIONS 239, 239 (2011) (mentioning that all states now screen for fifty-three core conditions to detect inherited metabolic diseases). This range of conditions includes what are described as twenty-nine core conditions and a secondary group of twenty-five targets that can be identified by screening for the core set. TIMMERMANS & BUCHBINDER, *supra* note 8, at 50, 63.

10. *See* Beth A. Tarini et al., *Waiving Informed Consent in Newborn Screening Research: Balancing Social Value and Respect*, 148C AM. J. MED. GENETICS 23, 23–24 (2008) (mentioning that "new NBS tests have rarely been subjected to population-based study" and demonstrating the difficulties of assessing risks and benefits).

11. *See* Andrews, *supra* note 2, at 58 ("Given the current state of development of medical genetics, . . . effective treatment for genetic disorders is rare . . . ."); Ellen Wright Clayton, *Currents in Contemporary Ethics: State Run Newborn Screening in the Genomic Era, or How to Avoid Drowning When Drinking from a Fire Hose*, 38 J.L. MED. & ETHICS 697, 698 (2010) (noting that for many of the reported results of newborn screening, "the efficacy and utility of therapeutic and preventative interventions are not clear").

12. Watson, *supra* note 6, at 18.

13. *See* Douglas Cnty. v. Anaya, 694 N.W.2d 601, 604 (Neb. 2005) (discussing the Anaya's argument that the requirement violated their "First Amendment right to free exercise of religion and their fundamental rights as parents").

14. *Id.* at 608 (concluding that the requirement did not "unlawfully burden the Anayas' right to freely exercise their religion" or "unlawfully burden their parental rights," mentioning the lack of evidence that the state had an anti-religious purpose in enforcing the law and the valid policy interests in addressing the health and safety of children born in Nebraska).

The more recent "Baby DNA Lawsuits"[15] have challenged the involuntary collection and dissemination of NBS samples to researchers for purposes other than NBS.[16] In Minnesota, the state Supreme Court ruled that the state's dissemination and use of newborns' DBS for research without obtaining written informed consent violated its Genetic Privacy Act.[17] Two similar lawsuits were brought in Texas. The state settled with the five plaintiff parents in the first suit after agreeing to destroy all samples collected without parental consent since 2002.[18] A class action filed in late 2010 in Texas was dismissed as moot because there was no evidence that the parties' newborn samples were actually used or distributed for research.[19]

I argue in this Article that these lawsuits and other developments in NBS should give pause to the presumption that parental consent is not necessary with respect to NBS. We already obtain much more information from NBS than we did in the past and we are on the cusp of being able to obtain substantially more information in the near future. Moreover, the nature of the information we will be able to glean will be of varied value, certainty, and complexity, raising issues not only about what diseases we should screen for, but whether parents should be required to consent to some or all parts of the NBS process. In addition, the fact that newborn samples are increasingly used for research, and that anonymization of biospecimens is increasingly difficult, supports the need to

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15. K.J. Mullins, *Bill to Ban Unauthorized Use of Infant DNA Clears Senate Committee*, DIGITAL J. (Feb. 11, 2010), http://www.digitaljournal.com/article/287446.

16. *See id.* (pointing out that NBS samples are used for unauthorized research).

17. Bearder v. Minnesota, 806 N.W.2d 766, 776 (Minn. 2011) (holding that there is no authority in the statute to disseminate blood samples or genetic information, without consent, "beyond that expressly authorized for the reporting of newborn test results"). *See generally* MINN. STAT. §13.386 (2010) (Minnesota's Genetic Privacy Act).

18. *See* Higgins v. Tex. Dep't of Health Servs., 801 F. Supp. 2d 541, 545–46 (W.D. Tex. 2011) (discussing the settlement of the earlier *Beleno* lawsuit, and the agreement to "destroy all blood specimens taken as part of the newborn screening program" prior to May 2009, for which no written consent existed); Allison M. Whelan, Note, *That's My Baby: Why the State's Interest in Promoting Public Health Does Not Justify Residual Newborn Blood Spot Research Without Parental Consent*, 98 MINN. L. REV. 419, 430–31 (2013).

19. *Higgins*, 801 F. Supp. 2d at 554 ("Plaintiffs never refute Defendants' evidence that Plaintiffs' children's blood samples were not distributed and have in fact been destroyed. Accordingly . . . their claims are now moot.").

rethink the role of consent in NBS, at least with respect to storage and research uses of DBS. As I will argue, the case for consent with respect to research also supports, in part, the notion of consent for NBS itself.

Yet, just as changing circumstances provide reasons to rethink parental consent with respect to NBS, the increasing scope of information we can glean from NBS makes the possibility of obtaining fully informed consent that much more problematic logistically, practically, and economically. In addition, the DBS are potentially valuable resources for research that can benefit the common good, generally, and the pediatric population, in particular. Thus, the question of consent in NBS raises issues about how to strike the right balance between the public good and private interests.

This Article offers a proposal for finding the right balance of consent for NBS itself, and for the storage and use of DBS. Part I offers a history of NBS and its evolution. Part II explores the rationales for the limited consent provisions for NBS as well as the growing practice of retaining these samples and using them for purposes that go beyond the original goals of NBS. Part III highlights the ways in which the public good comes into conflict with the private interests and describes a methodology that allows for these competing values to be recognized in policymaking. It concludes by suggesting that requiring affirmative consent for NBS and for research on DBS best balances the values of protecting the newborn's well-being and promoting research, while also protecting autonomy and privacy as much as possible.

## I. THE EVOLUTION OF NEWBORN SCREENING

NBS begins with a heel prick and the collection of a few drops of blood on filter paper, or Guthrie cards.[20] It is a preventive health measure that involves the analysis of the newborn's blood for various medical conditions, many of which are inherited, including certain inborn errors of metabolism and

20. *See* AGR, *supra* note 8, at 39 ("This test could be performed on a spot of blood obtained from a heel prick before the infant left the hospital nursery."). The Guthrie cards are named after Dr. Robert Guthrie, who developed the first NBS assay for phenylketonuria. Clayton, *supra* note 11, at 697; *Spotlight on NBS Researchers, Robert Guthrie, MD, PhD*, NEWBORN SCREENING TRANSLATIONAL RES. NETWORK, https://www.nbstrn.org/about/spotlight/Guthrie (last visited Mar. 6, 2014).

blood disorders.[21] The value of conducting screening during the newborn period is both practical and clinically significant. Most infants are born in hospitals, which makes the systematic collection of samples easier at this stage of life than nearly any other.[22] In addition, for many of the diseases screened, treatment must be started in the newborn period to prevent the development of clinical symptoms.[23]

As its name suggests, NBS is a *screening* program in which an abnormal result does not necessarily identify the presence of disease. It merely indicates an increased risk that the child has the condition, necessitating confirmation through diagnostic testing.[24]

With its inception nearly fifty years ago, NBS is the longest program of genetic screening in the history of genetics.[25] The first state program screened for phenylketonuria (PKU), a disease in which the child lacks a vital enzyme that breaks down the amino acid, phenylalanine.[26] Without this enzyme, phenylalanine can accumulate in the brain, causing mental retardation, unless the affected child eats a phenylalanine-free diet.[27] The first program, developed in Massachusetts, was

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21. *E.g.*, *Newborn Screening*, *supra* note 5.

22. *See* MARIAN F. MACDORMAN ET AL., NAT'L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, HOME BIRTHS IN THE UNITED STATES, 1990–2009, at 1 (2012) (showing that only 0.72% of births took place in the home in 2009).

23. *E.g.*, *Newborn Screening Tests*, KIDSHEALTH, http://kidshealth.org/parent/system/medical/newborn_screening_tests.html# (last visited Mar. 1, 2014) ("[E]arly diagnosis and proper treatment can make the difference between lifelong impairment and healthy development."); *see also* Clayton, *supra* note 11, at 697 (discussing the policy behind newborn screening and the rationale of "adding disorders to the newborn screening panel only if early detection and treatment could avert serious harm").

24. AGR, *supra* note 8, at 65 ("These screening tools are not definitive diagnostic tests, however, and positive results must be confirmed through specific testing for the disease in question.").

25. *See* Nancy S. Green et al., *Newborn Screening: Complexities in Universal Genetic Testing*, 96 AM. J. PUB. HEALTH 1955, 1955 ("Newborn Screening (NBS) is the first and largest example of systematic, populationwide genetic testing . . . .").

26. AGR, *supra* note 8, at 66.

27. *See id.* (stating that "high phenylalanine levels" can lead to mental retardation, and that a phenylalanine dietary restriction is "highly effective in preventing mental retardation"). The deficient enzyme is called phenylalanine hydroxylase. *Id.*

voluntary.[28] This is in sharp contrast, as I will address in Part II, to what is essentially mandatory screening in many states. Most states do not require affirmative parental consent under the theory either that the police powers justify this public health measure or under the doctrine of *parens patriae*.[29]

While PKU was the primary disease screened for in the early days of NBS, the panel of NBS diseases has expanded considerably in the last few years. The initial expansion, however, was quite slow, with only a few diseases added per decade.[30] As late as 2003, the number of diseases screened for in most states was still quite low—eight or fewer diseases.[31] Technological advances, however, changed that. While initial NBS required a separate assay for each disorder, the development of tandem mass spectrometry (MS/MS) in the 1990s allowed for the identification of over forty conditions through a single test,[32] contributing greatly to the expansion of

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28. *See* Newborn Screening Task Force, Am. Acad. of Pediatrics, *Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future—A Call for a National Agenda on State Newborn Screening Programs*, 106 PEDIATRICS 389, 389 (2000) [hereinafter NBSTF] ("By 1962, Massachusetts launched a voluntary newborn PKU screening program that demonstrated the feasibility of mass genetic screening."). Initially, "the American Medical Association (AMA) and its state organizations opposed mandatory screening as an infringement of physicians' rights to regulate their professional practice." TIMMERMANS & BUCHBINDER, *supra* note 8, at 38.

29. *See infra* Part II.A.

30. *See* Burke et al., *supra* note 8, at 149 (providing background information on the expansion of NBS).

31. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS 2 (2003) [hereinafter GAO], *available at* http://www.gao.gov/new.items/d03449.pdf ("While the number of genetic and metabolic disorders included in state newborn screening programs range from 4 to 36, most states screen for 8 or fewer disorders.").

32. *See* Cecilia I. Kaye et al., *Introduction to the Newborn Screening Fact Sheets*, 118 PEDIATRICS 1304, 1307, 1310 (2006) (discussing how MS/MS has led to additional disorders added to screening panels and the essential role played by pediatricians throughout the process). *See generally* Bridget Wilcken et al., *Screening Newborns for Inborn Errors of Metabolism by Tandem Mass Spectrometry*, 348 NEW ENG. J. MED. 2304, 2309 (2003) ("It is now possible to screen rapidly, simultaneously, and inexpensively for a number of very rare disorders with the use of tandem mass spectrometry."). Tandem mass spectrometry screens for inborn errors of metabolism by measuring the levels of various metabolites in the blood. *Id.* at 2305. Abnormalities in the levels of these metabolites suggest the presence of metabolic disorders. Mary Ann Baily & Thomas H. Murray, *Ethics, Evidence, and Cost in Newborn Screening*, HASTINGS CENTER REP., May–June 2008, at 23, 25. MS/MS can also screen for

NBS.[33] After several years of much variability in screening practices, a consensus began to emerge about the need for more uniformity in NBS, especially with respect to screening panels.[34] The American College of Medical Genetics (ACMG) issued recommendations for the standardization of the selection of NBS diseases in 2005, which were endorsed by several professional groups.[35] Now every state tests or will test for a minimum of twenty-nine conditions.[36] Some panels include over fifty disorders.[37]

As technologies allow us to test for more diseases more efficiently, the question of what diseases should be included in each state's NBS panel remains difficult and, as we shall see later, has some bearing on the question of whether parental consent should be required. Among the relevant criteria are, of course, scientific considerations, such as the prevalence of the condition in the population, the validity of the NBS test, and the efficacy of available treatments.[38] But other non-scientific considerations also play a vital role. Political concerns—such as

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PKU and other amino acid disorders, but it does not allow for the testing of all NBS disorders. Kaye et al., *supra* at 1310.

33. TIMMERMANS & BUCHBINDER, *supra* note 8, at 17. Interestingly, in the United Kingdom, "there was insufficient evidence and cost-effectiveness to support tandem mass spectrometry technologies for newborn screening," whereas in the United States, these factors did not inhibit the use of this technology because "cost-effectiveness is often neglected within health policy discussions, due to cultural anxieties about healthcare rationing." *Id.* at 58.

34. *Id.* at 34 ("The United States is one of only two industrialized countries without a national newborn screening policy.").

35. *Id.* at 50, 59. Although the report was one of the most controversial reports on NBS issued by an advisory body, it was also one of the most influential, in large part because it was strongly endorsed by such groups as the March of Dimes Foundation; The American Academy of Pediatrics; the Association of Women's Health, Obstetric and Neonatal Nurses; and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. *Id.* at 59.

36. *Id.* at 50; Watson et al., *supra* note 6, at 18 ("[T]he expert panel identified 29 conditions for which screening should be mandated."). I should note that I was part of the panel.

37. Moody & Choudhry, *supra* note 9, at 239 ("All states in the USA now screen for 53 core conditions . . . .").

38. The "classical" criteria used by states in determining which conditions to include in their NBS panels were derived from a seminal paper for the World Health Organization by Wilson and Jungner. *See* Heather Harrell, *Currents in Contemporary Ethics: The Role of Parents in Expanded Newborn Screening*, 37 J.L. MED. & ETHICS 846, 846–47 (2009) (discussing Wilson and Jungner's ten criteria to apply when considering population screening).

the existence of advocacy groups[39] and cost-benefit analysis[40]—are also hugely influential. And, of course, ethical considerations should and often do come into play.[41] For example, because the benefits to the newborn, to the family, and to society do not necessarily overlap, decision makers must decide whose benefits should determine the selection of the screening panel.

If the goal of NBS is to benefit the newborn, the panel of diseases should be limited to those for which we have effective treatments or early intervention and whose natural history we understand well. If we also consider the benefits to the family, however, the panel of diseases might be broader because it would include diseases with no treatment that might help parents make better informed reproductive decisions about

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39. In the context of NBS, parents have been strong advocates for expanding the array of tests. Advocacy and lobbying have been strong forces in the development and evolution of NBS. As Ellen Wright Clayton observes, NBS laws were influenced more by individual practitioners and political groups than anything else. Clayton, *supra* note 11, at 697–98 (discussing how most programs in the United States were driven by a report endorsed by the government committees and parent advocacy groups); *see* TIMMERMANS & BUCHBINDER, *supra* note 8, at 39, 44–48, 59–61 (describing the powerful role of advocacy in promoting NBS and its expansion).

40. *See* Harrell, *supra* note 38, at 846–47 (explaining that the criteria when considering population testing boils down to screening "illnesses that are sufficiently understood" and can be tested in a cost-effective manner). One of the reasons PKU screening was so widely applauded was its high cost savings of $93,000 per detected case. *Report of the NIH Consensus Development Conference on Phenylketonuria (PKU): Screening & Management: Chapter II*, NAT'L INST. CHILD HEALTH & HUM. DEV., https://www.nichd.nih.gov/publications/pubs/pku/Pages/sub30.aspx (last updated Dec. 21, 2011). The costs of screening per detected case, however, can sometimes be quite large. *See* OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTHY CHILDREN: INVESTING IN THE FUTURE 106–11 (1988) (demonstrating the variability in cost amongst different screening and testing strategies). Some groups, such as the March of Dimes, have taken the view that newborns should be screened regardless of how rare the disorder is, in essence rejecting considerations of cost-benefit analysis. *See Newborn Screening*, MARCH OF DIMES, http://www.marchofdimes.com/baby/newborn-screening.aspx (last visited Mar. 26, 2014) (expressing their desire for mandatory testing of extremely rare diseases, most of which, but not all, can be treated or dealt with). This perspective is more political or ethical than scientific, since it may not result in the greatest health benefit to the community, though it is quite a sympathetic position from the perspective of the individual families who benefit from such an approach. *See* Press Release, N.Y. Dep't of Health, State Health Department Receives March of Dimes Award for National Leadership in Newborn Screening (Dec. 14, 2007) (lauding New York's comprehensive NBS program).

41. *See infra* text accompanying notes 42–44.

whether to undergo prenatal testing with future pregnancies.[42] In addition, such information can avoid diagnostic odysseys, when parents search long and hard for the diagnosis of a rare condition.[43] Finally, if we focus on the benefits to society, the panel of diseases would be even larger, including conditions about which we have limited knowledge and no effective treatments so that we can identify potential research subjects to learn more about the natural history of the disease.[44]

For some time, the consensus has been that the benefits to the newborn should be decisive in selecting conditions for NBS since the *raison d'être* of the program is to protect infants from debilitating diseases.[45] Despite this consensus, these criteria have not always been followed in practice.[46] Because state health departments have substantial discretion to decide which

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42. Many parents would seek prenatal testing with future pregnancies, even if they did not plan to terminate affected pregnancies. Peter T. Rowley, *Parental Receptivity to Neonatal Sickle Trait Identification*, 83 PEDIATRICS 891, 892 (1989) (noting that most women at risk for having a child with sickle cell anemia wanted prenatal testing even though only one quarter would terminate the pregnancy if the fetus were affected). *But see* Ranjeet Grover et al., *Newborn Screening for Hemoglobinopathies: The Benefit Beyond the Target*, 76 AM. J. PUB. HEALTH 1236, 1236–37 (1986) (reporting that fourteen out of twenty-three women at risk for having a child with sickle cell anemia had an amniocentesis and three of the four affected pregnancies were terminated). Some have observed that this rationale for NBS makes it less about protecting the newborn and more about eugenic goals of eradicating undesirable conditions in the population. *See, e.g.*, TWILA BRASE, CITIZENS COUNCIL ON HEALTH CARE, NEWBORN GENETIC SCREENING THE NEW EUGENICS? THE CASE FOR INFORMED CONSENT REQUIREMENTS FOR GENETIC TESTING, BABY DNA STORAGE AND GENETIC RESEARCH 1 (2009), *available at* http://www.cchfreedom.org/pr/NBS_EUGENICS_REPORT_Apr2009_FINAL.pdf.

43. Baily & Murray, *supra* note 32, at 28–29.

44. TIMMERMANS & BUCHBINDER, *supra* note 8, at 51 (describing how consideration of not just individual benefits, but also benefits to the family and society is an example of "'benefit creep'").

45. *See* J.M.G. WILSON & G. JUNGNER, WORLD HEALTH ORG., PRINCIPLES AND PRACTICE OF SCREENING FOR DISEASE 14 (1968) (stating that the aim of early detection is to protect the individual). For a broader discussion and criticism of the shift in focus of some NBS programs from benefit to the infant to benefit to the family and society, see generally PRESIDENT'S COUNCIL ON BIOETHICS, THE CHANGING MORAL FOCUS OF NEWBORN SCREENING: AN ETHICAL ANALYSIS BY THE PRESIDENT'S COUNCIL ON BIOETHICS (2008), *available at* http://bioethics.georgetown.edu/pcbe/reports/newborn_screening/index.html (discussing the shift from focusing primarily on what benefits the infant to a "*broader conception of benefit*").

46. *See generally* COMM. FOR THE STUDY OF INBORN ERRORS OF METABOLISM, NAT'L ACAD. OF SCIS., GENETIC SCREENING: PROGRAMS, PRINCIPLES AND RESEARCH 228 (1975) (listing unacceptable aims of NBS).

tests to include for NBS, there is little oversight.[47] Even the ACMG recommendations, which expressly declare that the benefit to the newborn should drive the selection of disease,[48] include a panel of diseases, not all of which directly or indirectly benefit the newborn.[49]

Several factors have contributed to, and will likely further contribute to, the expansion of NBS, not all of which directly benefits the newborn. Technological advances, such as MS/MS, have contributed to this expansion.[50] Other technologies, like DNA microarrays, will make it possible to screen for a slew of genetic conditions.[51] With the possibility of ever-cheaper whole genome sequencing, it is not hard to imagine a time, in the not too distant future, when NBS will be expanded to include whole genome sequencing.[52] Indeed, the National Institutes of Health (NIH) recently funded pilot programs to "explore the promise—and ethical challenges—of sequencing every newborn's

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47. *See* AGR, *supra* note 8, at 67 (stating that typically state health departments have broad discretion to introduce tests, often with little oversight, which can lead to testing for genetic conditions with little clinical significance).

48. Watson et al., *supra* note 6, at 2S. The approach to selecting diseases awarded points for clear benefits to family and society, as well as points for individual benefits, which were weighted more heavily. TIMMERMANS & BUCHBINDER, *supra* note 8, at 51–52.

49. Specifically the group proposed mandated screening for a panel of twenty-nine conditions and suggested that an additional twenty-five be reported to families. Watson et al., *supra* note 6, at 1S. Because there is no treatment for some of these diseases, they did not meet the standard criteria for NBS. Baily & Murray, *supra* note 32, at 26; Watson et al., *supra* note 6, at 1S; *see also* Jeffrey R. Botkin et al., *Newborn Screening Technology: Proceed with Caution*, 117 PEDIATRICS 1793, 1796 (2006) (discussing the issues with offering results for a large number of conditions for which limited or no evidence of benefits exist).

50. This would not be the first time that medical diagnostics have been driven as much or more by technology than by need. *See* Sonia Mateu Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 233 (2002) ("A product of the technology era, genetics has, in a short time, offered vast amounts of information.").

51. DNA microarrays allow researchers to analyze thousands of active genes at a time, which could allow them to search for huge numbers of genetic disease mutations at one time. *DNA Microarray Technology*, NAT'L HUM. GROWTH RES. INST. (Nov. 15, 2011), http://www.genome.gov/10000533.

52. *See* FRANCIS S. COLLINS, THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALIZED MEDICINE 208 (2010) ("[It is] almost certain . . . that complete genome sequencing will become part of newborn screening in the next few years.").

genome."[53] This is consistent with the development of personalized medicine and the belief that it is responsible and empowering to get as much medical information as possible.[54]

So far, most of the expansions of NBS have been beneficial, although the data about "long-term clinical outcomes" are limited.[55] The lives of many children, who might have died years ago because their state did not screen for medium chain acyl-coenzyme A dehydrogenase deficiency (MCADD), for example, have been saved by the introduction of MCADD testing in all states.[56] Even so, the expansion of NBS is not without costs. The more conditions we screen for, the greater the risk of the inevitable artifacts of any screening program: false negatives, false positives, and clinical and diagnostic uncertainty. False negatives may create false reassurance and slow the process of diagnosis; because pediatricians know that NBS is done for all children, they may assume that the child does not have one of the NBS diseases based on the negative NBS result.[57]

False positives present the opposite problem.[58] When a child is reported as being positive for one of the NBS conditions,

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53. Jocelyn Kaiser, *NIH Studies Explore Promise of Sequencing Babies' Genomes*, SCI. MAG. (Sept. 4, 2013, 2:45 PM), http://news.sciencemag.org/biology/2013/09/nih-studies-explore-promise-sequencing-babies%E2%80%99-genomes.

54. *See* Suter, *supra* note 50, at 233–34 (noting the strong desire to use technology to get as much information as possible, but also cautioning that knowledge can be toxic at times).

55. TIMMERMANS & BUCHBINDER, *supra* note 8, at 184.

56. *See* Baily & Murray, *supra* note 32, at 23–24 (discussing Mississippi's response to MCADD and the benefits to its newborn population). However, not all deaths due to MCADD have been eliminated with NBS. *See* TIMMERMANS & BUCHBINDER, *supra* note 8, at 185.

57. False negatives can occur because of failures in the administration of NBS: failure to perform the test properly, to record the results, or simply to test. But false negatives can also occur even if everything is done correctly because NBS is a *screening* test—it is not diagnostic. AGR, *supra* note 8, at 40. False negatives may have become less of a problem in the last five to ten years, but state health departments recognize the possibility of false negatives. ARIZ. DEP'T OF HEALTH SERVS., ARIZONA NEWBORN SCREENING PROGRAM: GUIDELINES 42–43 (2010), *available at* http://www.azdhs.gov/lab/aznewborn/documents/providers/AZ-Newborn-Screening-Provider-Guidelines.pdf (revised Jan. 2011).

58. False positives may result from errors in the testing process (testing/analysis or reporting), but in general, false positives are an unavoidable consequence of screening for extremely rare disorders. But like false negatives, they are also inevitable artifacts of any screening program. The

the family can experience a great deal of anxiety and confusion. Some studies have shown that false positives can have an adverse effect on the relationship between parent and child, including parents' continued worries about the child's health even after learning that she did not have the condition after all.[59] In addition, false positives may have a negative health impact on the child by requiring follow-up testing and treatment until it is determined that the child is unaffected; further testing and treatment both pose potential medical risks.[60] Children who have false positive results are often mislabeled as ill even though they do not display any clinical symptoms.[61]

The recent and rapid expansion of NBS panels may also result in the diagnosis of conditions for which there is no treatment, which may create unnecessary stress and anxiety for the family and affect the parent-child relationship. For example, parents may pursue costly treatment odysseys, hoping to find a cure even though no proven treatment exists.[62] While such information may help parents with future reproductive decision making, this rationale moves NBS away from its stated purpose of benefitting the newborn. Moreover, it undercuts the

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incidence of false positives can be quite high. "Some states have a [positive predictive value] of only 3%, meaning that 97% of infants who initially test positive do not actually have the disease." Whelan, *supra* note 18, at 438.

59. *See* K. Fyrö & G. Bodegård, *Four-Year Follow-up of Psychological Reactions to False Positive Screening Tests for Congenital Hypothyroidism*, 76 ACTA PAEDIATRICA SCANDINAVICA 107, 107, 111 (1987) (finding that a significant portion of families experienced persistent anxiety months and years after false positives); James R. Sorenson et al., *Parental Response to Repeat Testing of Infants with 'False-Positive' Results in a Newborn Screening Program*, 73 PEDIATRICS 183, 185–86 (1984). One study also found that about half of the children demonstrated difficulty adjusting psychologically to the false positives as the mother-child relationship was negatively impacted. Karin Fyrö & Göran Bodegård, *Difficulties in Psychological Adjustment to a New Neonatal Screening Programme*, 77 ACTA PAEDIATRICA SCANDINAVICA 226, 229–31 (1988) (noting, however, that other factors may have played a role in the dysfunction, which were unveiled by the NBS results).

60. Harrell, *supra* note 38, at 847–48 (describing the general concern and her family's experience with a false positive when her son was screened as a newborn).

61. *Id.* at 847 (discussing the effects of a ten to one ratio of false positives to true positives, coupled with a lack of visible symptoms, on parents' decision making, and the fact that false positives create the belief that the child is ill and that it is neglectful not to proceed with additional testing).

62. *See* Baily & Murray, *supra* note 32, at 28–29.

justification for the mandatory nature of NBS, as we shall see in Part III.B.

Even more complicated issues arise when laboratories make incidental findings of "abnormalities" or clinically ambiguous findings.[63] This problem has increased with tandem mass spectrometry, which looks for a group of core conditions by identifying unusually high levels of metabolites related to these conditions.[64] An artifact of this technology is the incidental identification of elevated levels of certain metabolites, which the laboratory was not even trying to identify,[65] or the identification of screening values that lie outside the normal range but that do not always clearly correlate with defined disease categories.[66] These findings can lead to a new kind of diagnostic odyssey, where children become, to use the terminology of Timmermans and Buchbinder, "patients-in-waiting," who hover "for extended periods of time under medical attention between sickness and health, or more precisely, between pathology and an undistinguished state of 'normality.'"[67]

Several problems arise when these incidental or diagnostically uncertain findings are made and reported to

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63. TIMMERMANS & BUCHBINDER, *supra* note 8, at 12 ("Newborn screening is a technology expected to provide actionable knowledge, yet it generates uncertainty in the clinic . . . .").

64. Baily & Murray, *supra* note 32, at 25 ("Tandem mass spectrometry measures the levels of various metabolites in the blood, and abnormalities in the levels suggest the presence of metabolic disorders.").

65. TIMMERMANS & BUCHBINDER, *supra* note 8, at 104 (describing the identification of ACADM variants of unknown significance). Indeed, one of the debated aspects of MS/MS is how many of the metabolic variants to report to families. The ACMG proposed that in addition to a core panel of twenty-nine conditions identified through MS/MS, twenty-five others should be disclosed to families. *See supra* note 49. Some countries report only a limited number of conditions identifiable through MS/MS. Clayton, *supra* note 11, at 697 ("Many countries have chosen to report only a limited number of disorders detectable by MS/MS . . . ."). The argument for this approach is that, if the family knows about these conditions, they might avoid diagnostic odysseys. In addition, such information might be useful for reproductive decision making, and following such children might help us deepen our understanding of these conditions. These arguments, however, depart from the traditional NBS philosophy by placing societal benefits above the needs of the child. Baily & Murray, *supra* note 32, at 28. On the other hand, not everyone wants such information and there can be harm in receiving ambiguous information or information about conditions for which there is no treatment. *See* Clayton, *supra* note 11, at 698 ("Some parents simply will not want all these results.").

66. TIMMERMANS & BUCHBINDER, *supra* note 8, at 65.

67. *Id.*

parents. The child might be stigmatized as a "sick child" before symptoms develop, if they ever will. This label has been shown to have a harmful effect on the parent-child relationship and on the family as a whole.[68] Indeed, in some cases, the child might never become clinically affected by the abnormal levels of the metabolite or the mutation.[69] There may be a considerable time lag before physicians can determine whether high metabolites or certain mutations are clinically significant, hence the phrase "patients-in-waiting."

Timmermans and Buchbinder's ethnographic study of a genetics clinic describes the complexities and anxieties that such diagnostic uncertainties present and the ways in which entire families are affected during this period.[70] If families learn of these findings, they might embark on treatment odysseys, investing significant money and time in search of treatments that may not exist or that are unproven. Sometimes the heightened vigilance that parents exhibit during this period is difficult to "tone down" once it becomes clear that the child is not clinically affected.[71] NBS programs may also spend added dollars to report and follow up on conditions for which treatments may not exist. It has also presented challenges for clinicians who have to contend with the fact that expanded screening has "identified more patients than anticipated," most of whom are asymptomatic, and which requires a collective

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68. *See supra* note 59.

69. In fact, with little knowledge of the disease's natural history, it is difficult to know the rate of false positives or negatives or even, at times, to determine whether there is a false positive or negative.

70. TIMMERMANS & BUCHBINDER, *supra* note 8, at 65–96 (describing the full experience of "patients-in-waiting" and their families).

71. *Id.* at 88 ("When, after time passed, the baby remained fine, clinicians sometimes had trouble getting the parents to tone down their level of vigilance."); *id.* at 91 ("[W]hile geneticists could be ready to let the condition fade away, family members could nevertheless perpetuate the medicalization of their child."); *id.* at 226 ("The most striking emotion we observed in the clinic was anxiety, but parents also expressed shame, anger, and sadness."). Even so, "nearly all of the families in [Timmermans and Buchbinder's] study regarded the screening program favorably." As one parent said, "[w]e would rather go through 10 weeks of the hell we went through than a lifetime of having a special needs child without having the opportunity to know from day one or day five." *Id.* at 219.

learning process and the development of new knowledge to determine who is truly affected.[72]

If NBS ultimately includes whole genome sequencing, similar issues will arise on an even greater scale. We are unlikely to fully understand for some time the clinical implications of many mutations, let alone the complex interactions of different mutations within a particular genome and environment. In many instances, it will be difficult to determine whether a genetic variant is likely to have a significant clinical impact, or what the degree or timing of such impact would be.[73] As a result, whole genome sequencing would likely provide a great deal of data of limited value, which could increase parental anxiety and confusion.

Although the *raison d'etre* for NBS was to promote the wellbeing of newborns, some of the expansions of NBS can only be justified by other considerations, such as allowing parents to make better informed reproductive decisions and benefiting society by allowing us to better understand the conditions. The more these other rationales are used to justify expansions of NBS, the more we should question whether screening infants without the consent of parents can be justified. I turn now to an explanation for the enduring lack of consent in NBS before discussing the issues of consent that arise with respect to the storage and dissemination of newborn samples for research and other uses.

## II. THE LACK OF CONSENT IN NBS

Consent has long been absent in NBS, making it in essence a mandatory screening program. Recently, the public and scholarly communities have focused largely on the lack of consent with respect to the storage and future uses of DBS. But although the lack of consent with respect to the collection of blood samples and screening itself has not been challenged as strongly, there are reasons to question the presumption against requiring consent for NBS itself. I begin by describing the general rationales for lack of consent in NBS and then turn to the practices with respect to storage and future uses before

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72. *Id.* at 94–95; *see id.* at 119 ("[E]xpanded newborn screening has prompted a tremendous knowledge explosion about rare metabolic conditions.").

73. Clayton, *supra* note 11, at 698.

offering my recommendations, in Part III, regarding consent in these two areas.

### A. CONSENT (OR LACK THEREOF) FOR NEWBORN SCREENING ITSELF

NBS is quite unusual in being one of the few areas where the state can require medical testing of an individual or child without affirmative consent.[74] Even so, the mandatory nature of NBS has long been well accepted with only minimal criticism.[75] Although most states do not require affirmative parental consent for newborn screening, there is some variability with respect to what amounts to presumed consent. The majority of states allow parents to opt out, although the reasons they allow differ. Some will only allow parents to refuse for religious reasons.[76] Many will allow parents to opt out for any reason.[77] At one extreme, NBS is mandatory without exception.[78] One state actually imposes criminal penalties for refusing to undergo NBS.[79] Even in states where there is an opt-out provision, there is serious doubt as to whether parents truly have an opportunity to refuse in these jurisdictions,[80] making

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74. Parents are generally allowed to refuse medical treatment or testing on behalf of their child, unless their decision puts a child at grave risk. *See* Andrews, *supra* note 2, at 59 ("Only when their decisions put their children at grave risk are parental decisions overridden by the state.").

75. *See, e.g.*, Clayton, *supra* note 11, at 697 (discussing the rapid development of the screening programs and stating that they "were almost always mandatory, in response to advocacy by geneticists and parents").

76. *See* TENN. CODE ANN. § 68-5-403 (2013) (allowing parents to opt out of testing or medical treatment if they file a written statement that states such tests or treatment conflict with their "religious tenets and practices"); WIS. STAT. ANN. § 253.13(3) (West 2010) (stating that the statute shall not apply "if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices").

77. *See, e.g.*, FLA. STAT. ANN. § 383.14(4) (West 2007) ("The provisions of this section shall not apply when the parent or guardian of the child objects thereto."); N.M. STAT. ANN. § 24-1-6(A) (West 2011) (stating that parents, after being informed of the reasons for the tests, may waive the requirements for the tests in writing).

78. MICH. COMP. LAWS ANN. § 333.5431 (West 2001); MONT. CODE ANN. §§ 50-19-201 to -211 (2013); NEB. REV. STAT. §§ 71-519 to -524 (2009); S.D. CODIFIED LAWS §§ 34-24-17 to -25 (2011); W. VA. CODE §§ 16-22-1 to -6 (2010).

79. S.C. CODE ANN. § 44-37-30(G) (1991).

80. Ruth Faden et al., *A Survey to Evaluate Parental Consent as Public Policy for Neonatal Screening*, 72 AM. J. PUB. HEALTH 1347, 1347 (1982) (describing the screening as "compulsory for all practical purposes").

the provision "opt-out" more in name than practice. Only two states require affirmative parental consent.[81]

Not only is a requirement of consent for NBS rare, but parents are often woefully uninformed about NBS. Often states provide limited information about the nature of NBS testing[82] or that there is an option to opt out (when there is such an option).[83] Sometimes parents are not even informed that the child will be tested.[84] If a child tests positive through NBS, parents often do not learn that the newborn *screening* results are not diagnostic and that there may be false positives or negatives.[85] And many are not adequately educated about the nature of the condition or offered genetic counseling, even when the child tests positive.[86]

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81. D.C. CODE §§ 7-831 to -840 (LexisNexis 2012); WYO. STAT. ANN. §§ 35-4-801 to -802 (2013). In the last few years, Maryland switched from its opt-in, informed consent approach, to an opt-out approach. *See* MD. CODE REGS. 10.52.12.07 (2013); Rachel L. Schweers, *Newborn Screening Programs: How Do We Best Protect Privacy Rights While Ensuring Optimal Newborn Health?*, 61 DEPAUL L. REV. 869, 891 n.130 (2012). The rationale for this change was to bring testing in line with the national Newborn Screening Taskforce, to be like the vast majority of states, and to lighten the paperwork burden on hospitals and providers because parental refusal is so rare. MD. DEP'T OF HEALTH & MENTAL HYGIENE, 2008 LEGISLATIVE REPORT: SHOULD A COORDINATED STATEWIDE SYSTEM FOR SCREENING NEWBORN INFANTS BE APPLIED TO ALL NEWBORN INFANTS IN MARYLAND? 2–3 (2008).

82. *See* Schweers, *supra* note 81, at 869 (discussing the lack of knowledge about screening policies amongst health care providers, and the need to initiate a discussion in order to address concerns).

83. *See, e.g.*, MD. CODE REGS. 10.52.12.07 (2013) (providing an example of an opt-out regulation); Rachel Grob, *Parenting in the Genomic Age: The 'Cursed Blessing' of Newborn Screening*, 25 NEW GENETICS & SOC'Y 159, 159, 163 (2006).

84. AGR, *supra* note 8, at 67 (stating that at this point, most parents receive brochures or some general information at the time of screening, although in many cases this is very thin, token information); *see* Terry C. Davis et al., *Recommendations for Effective Newborn Screening Communication: Results of Focus Groups with Parents, Providers, and Experts*, 117 PEDIATRICS S326 (Supp. May 2006) (providing that one-third of patients in a study in California never received NBS materials from their prenatal providers even though California requires them to provide patients with such information); Lisa A. Faulkner et al., *The Newborn Screening Educational Gap: What Prenatal Care Providers Do Compared with What Is Expected*, 194 AM. J. OBSTETRICS & GYNECOLOGY 131 (2006).

85. AGR, *supra* note 8, at 65, 67.

86. *See* Clayton, *supra* note 11, at 697 ("While some people may value this information, other parents who specifically chose not to have carrier screening for themselves may be less pleased when they involuntarily learn their carrier status from their child's newborn screen.").

NBS laws and practices go very much against legal and ethical norms in the United States, which recognize an individual's right to choose whether to undergo medical treatment or testing and to refuse treatment even when it can result in death.[87] Not only is consent required for most medical interventions and treatments,[88] generally consent must be *informed*.[89]

There is considerable irony in the fact that parental decision making and education are so limited with NBS since it is essentially a form of *genetic* screening. Mandatory genetic testing is extremely unusual,[90] in large part because a strong consensus has existed for some time that genetic screening programs should not be compulsory and should involve informed consent.[91] After all, genetics and especially genetic counseling are among the disciplines in medicine most deeply committed to individual autonomy in medical decision making and informed decision making for genetic testing.[92]

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87. The Supreme Court, in *Cruzan v. Mo. Dep't of Health*, 497 U.S. 261, 269–70 (1990), discussed the long common law tradition of protecting bodily integrity through battery actions and the informed consent doctrine, which is now "firmly entrenched in American tort law." Based on this common law tradition, the court inferred that a competent person has a constitutionally protected right to refuse lifesaving hydration and nutrition. *See* Winston v. Lee, 470 U.S. 753, 753, 766 (1985) (holding the surgical removal of a bullet from a defendant's body was an unreasonable search violating the Fourth Amendment); Rochin v. California, 342 U.S. 165, 172–73 (1952) (holding that evidence obtained through the forceful use of a stomach pump violated the Due Process Clause).

88. Treating a patient or imposing some medical intervention without a patient's consent could easily be the basis for a battery claim. BARRY R. FURROW ET AL., HEALTH LAW: CASES MATERIALS AND PROBLEMS 357–58 (5th ed. 2004).

89. *Id.* at 357.

90. Andrews, *supra* note 2, at 58 (providing that some unfortunate exceptions to this rule have included the mandatory testing for carriers of the gene for sickle cell anemia); *see* AGR, *supra* note 8, at 40–42.

91. Faden et al., *supra* note 80, at 1347–48 (describing various policy committees that have expressly rejected "public health justification[s] for mandatory [genetic] screening" and noting that "[t]he Genetic Disease Title of Public Law 94-278, which provides assistance in the establishment of genetic testing and counseling programs, requires that the 'participation by an individual in any program or portion thereof under this part shall be wholly voluntary'").

92. *See* TIMMERMANS & BUCHBINDER, *supra* note 8, at 19 (noting how inconceivable it seems in "an era infused with bioethical concern about patient autonomy and genetic discrimination" to screen "the overwhelming majority of

NBS is not, however, the only example in which the state has made medical decisions on behalf of individuals. The state has intervened either to protect the well-being of the public or the individual himself. In *Jacobson v. Massachusetts*, for example, the Supreme Court upheld the state's right to mandate its citizens to be vaccinated against smallpox.[93] The Court reasoned that vaccinating an individual against his will did not violate the individual's liberty interests.[94] This was so because a "community has a right to protect itself against an epidemic of disease which threatens the safety of its members,"[95] as long as the means of doing so are "reasonably required for the safety of the public."[96] The court located the state's right to compel vaccination within its police powers because it protects the public health[97] by preventing the spread of highly contagious smallpox.[98] The state has also exercised its police powers to impose medical treatment against a person's will when someone has been deemed mentally ill and a threat to others.[99] In both instances, the government intervenes to prevent one individual from threatening physical danger or harm to another.[100] In spite of possessing these potentially broad powers, the states have tended to be fairly limited in using them.[101]

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infants . . . for *genetic* conditions without informed consent"): Suter, *supra* note 50, at 242–43.

93. Jacobson v. Massachusetts, 197 U.S. 11, 38–39 (1905).

94. *Id.* at 27.

95. *Id.*

96. *Id.* at 28.

97. *Id.* at 24–25 ("The authority of the State to enact this statute is to be referred to what is commonly called the police power—a power which the State did not surrender when becoming a member of the Union under the Constitution. [T]his court . . . has distinctly recognized the authority of a State to enact quarantine laws and 'health laws of every description;' . . . . According to settled principles, the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.").

98. *Id.* at 35 (finding "strong support" for the view that vaccination is an effective "means of protecting a community against smallpox").

99. Washington v. Harper, 494 U.S. 210, 236 (1990).

100. Ellen Wright Clayton, *Screening and Treatment of Newborns*, 29 HOUS. L. REV. 85, 126 (noting that the police power "has historically been invoked only to protect others from physical harm").

101. Andrews, *supra* note 2, at 54 (noting, for example, that the government has not tended to track people down with infectious diseases, quarantined them, or forced them to undergo treatment, but observing that in some limited

The mandatory nature of NBS has been justified by these police powers because NBS is touted as a public health effort.[102] In fact, however, NBS does not neatly fit into this model. NBS screening is conducted primarily to prevent harm to the *individual* who is being screened, rather than to prevent harms to others.[103] To be sure, identifying a child's metabolic disorder in time to provide treatment can minimize suffering for the family overall, reduce societal health care costs, and expand families' reproductive options. These rationales, however, are not typically what we think of as public health efforts of the sort that justifies the police powers. Of course, if we conceive of the public health more broadly as the public good, then this justification is more powerful.

Even so, the better rationale for the mandatory nature of NBS is the doctrine of *parens patriae*, which allows the state to limit a person's liberty to protect the individual.[104] The basic principle of this doctrine is to preserve human life.[105] Although there is a common law and constitutional presumption that parents have the right to make medical decisions on behalf of their children,[106] the state can intervene if parental decisions constitute abuse or neglect.[107] Classic cases in which the state

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cases people have been required to be tested to HIV infection if convicted of certain crimes).

102. Faden et al., *supra* note 80, at 1347.

103. Whelan, *supra* note 18, at 435 (describing the police powers as infringing "on individual rights primarily to protect the public from other individuals' actions or behaviors").

104. STEVEN OLSON & ADAM C. BERGER, INST. OF MED., CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH: WORKSHOP SUMMARY 7 (2010) ("Newborn screening programs are authorized through the legal doctrine known as *parens patriae*, which gives the state the right to assume certain roles of parents based on benefits to the child and to society as a whole."); Clayton, *supra* note 100, at 126.

105. Newmark v. Williams, 588 A.2d 1108, 1115 (Del. 1991).

106. *Id.* at 1115–16 ("[T]he common law recognizes that the only party capable of authorizing medical treatment for a minor in 'normal' circumstances is usually his parent or guardian."); *e.g.*, Santosky v. Kramer, 455 U.S. 745, 753 (1982); Parham v. J.R., 442 U.S. 584, 602 (1979).

107. *Newmark*, 588 A.2d at 1116 ("[T]he State can intervene in the parent-child relationship where the health and safety of the child and the public at large are in jeopardy."); BARRY R. FURROW ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS (6th ed. 2008); Lainie F. Ross, *Predictive Genetic Testing of Children and the Role of the Best Interest Standard*, 41 J.L. MED. & ETHICS 899, 901 (2013) (noting that in the United States, as compared with the United Kingdom, the best interest standard tends to give "'considerable deference to

has successfully intervened include parental decisions to withhold lifesaving transfusions or chemotherapy.[108]

The *parens patriae* justification for NBS is the urgent need for early diagnosis of conditions for which early treatment can reduce morbidity and mortality. It is further supported by the fact that the risks of testing and treatment are generally minimal. Thus, the argument goes, the state must intervene because parental refusal to test for various inborn errors of metabolism and other serious conditions could be potentially life threatening or seriously debilitating by preventing an affected child from being diagnosed during the newborn period. The underlying presumption is that without a mandate, parents will refuse to participate in NBS, leaving children undiagnosed and therefore untreated for treatable conditions.[109] Because NBS fits better within a medical model—where the focus is the risk/benefit calculus with respect to the individual—than a public health model, the *parens patriae* justification is more appropriate than the police powers rationale.

Even so, as some scholars pointed out in the earlier years of NBS, and as is even truer now as NBS expands, the *parens patriae* rationale is somewhat questionable for many reasons. First, as I discuss in Part III, empirical data challenge the presumption that a mandate is necessary to ensure that newborns are screened. Second, definitive treatments are not available for all of the conditions identified;[110] a problem that

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childrearing decisions made by parents or guardians, with state intervention generally confined to instances of abuse or neglect'") (citing Lainie F. Ross et al., *Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children*, 15 GENETICS MED. 234, 236 (2013)); June Carbone, Legal Applications of the "Best Interest of the Child" Standard: Judicial Rationalization or a Measure of Institutional Competence 10 (unpublished manuscript) (on file with author) (noting that, although "the treatment of children starts with deference toward parental preferences" parental rights "are not absolute").

108. Andrews, *supra* note 2, at 59; Seema Shah, *Does Research with Children Violate the Best Interests Standard? An Empirical and Conceptual Analysis*, 8 NW. J.L. & SOC. POL'Y 121, 125, 156 (2013) (finding that courts ordered blood transfusions over parental objections in all but two cases).

109. *See* PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL RESEARCH, A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS (1983), *available at* http://kie.georgetown.edu/nrcbl/documents/pcemr/geneticscreening.pdf.

110. *See* TIMMERMANS & BUCHBINDER, *supra* note 8, at 183 (describing how the genetics clinic saw many "symptomatic patients who did not seem to

will likely grow as the panel of diseases expands. Third, in some cases interventions can save lives, but the children still "face significant developmental delays, frequent hospitalizations, and serious risks of mortality."[111] Sometimes, newborn screening may not occur in time to protect those at greatest risk.[112] Given the ongoing morbidity and mortality for many children screened positive, some scholars predict that "the health payoff of screening is likely to be lower than the number of true positive might otherwise imply."[113]

Even when treatments are available, the state often does not actually provide treatment to the affected children; the programs merely provide families with the information to seek out treatment.[114] The success of newborn screening in preventing disease depends largely on day-to-day efforts to manage the conditions and "the ability [of families] to tap into available medical services and social resources," which is as much a function of socioeconomic factors as anything else.[115] As

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improve" and how "for the most severe disorders associated with the worst outcomes . . . newborn screening [is] unlikely to make a difference in outcomes"); Clayton, *supra* note 11, at 698 ("Other disorders are identified for which there is no effective therapy.").

111. TIMMERMANS & BUCHBINDER, *supra* note 8, at 179; *id.* at 184 ("[S]ome children did poorly despite the advance knowledge provided by newborn screening."); *id.* at 189 (describing conditions for which early interventions "could prevent only some negative consequences").

112. *Id.* at 162 ("[B]etween July 2005 and April 2009, 62 screen positive infants died in California before follow-up care could be started in a metabolic center."); *id.* at 180 ("In some cases, newborn screening results arrived too late, after a child had already sustained a devastating metabolic crisis and permanent brain damage.").

113. *Id.* at 216.

114. *See* Burke et al., *supra* note 8, at 152 ("Although most states provide informational brochures, many parents are unaware that their infant has been tested unless they are notified of a positive result."); *see also* R. Rodney Howell, *We Need Expanded Newborn Screening*, 117 PEDIATRICS 1800, 1802 (2006) ("The facilities vary widely for such follow-up around the country, and it is incumbent on the state programs to work in their regions to provide follow-up support in terms of funding and organization."). In such cases, we may simply be labeling more children as ill without actually providing much clinical benefit to many of these children, especially if parents are not adequately educated or cannot afford the treatment. Moreover, it exacerbates concerns about whether the resources devoted to NBS could be better used to address the urgent health care needs of many children that have still not been met.

115. TIMMERMANS & BUCHBINDER, *supra* note 8, at 195; *see id.* at 170, 194–210 (describing the effects of insurance, access to transportation, language, education and bureaucratic barriers on parents' abilities to manage their children's metabolic conditions).

a result, the state's efforts work only partially toward the goal of eliminating the deleterious effects of the diseases, leading some to question whether the true motivation for mandatory NBS is actually the well-being of the child.[116]

Finally, even if the state is motivated primarily by the well-being of each child, it is not clear that the risks are great enough to justify state intervention. While many of the NBS conditions could lead to grave, even life-threatening, harm if undetected, these conditions are extremely rare. This means that the probability that any one child who is not tested through NBS will suffer a grave or life-threatening illness by failing to undergo NBS is statistically quite low, although clearly the magnitude of harm could be quite great.[117] In contrast, both the probability and magnitude of harm (death or serious debilitation) in failing to provide blood transfusions or chemotherapy, for example, will often be considerable.[118] As Professor Lori Andrews has noted, the risks of refusing NBS screening "is far less than the risks inherent in many other decisions that parents are routinely allowed to make," such as allowing their children to play on high school sports teams.[119] Moreover, the probability of false positives is quite high; the rate of false to true positives can be as high as, or higher than, ten to one.[120] As noted above, false positives are often not inconsequential. They can potentially lead to psychological,

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116. *See* Burke et al., *supra* note 8, at 151 ("However, growing test capacity has led to calls to expand not only the number of disorders screened for but also the goals of newborn screening."). "In the past, . . . infrastructural problems and healthcare costs had tempered enthusiasm for expanding newborn screening, but the separation of the scientific issues from those affecting healthcare delivery had the effect of decontextualizing the viability of screening." TIMMERMANS & BUCHBINDER, *supra* note 8, at 55.

117. NBSTF, *supra* note 28, at 414.

118. Andrews, *supra* note 2, at 60. Of course, the calculus can often be complicated by other factors. In *Newmark v. Williams*, 588 A.2d 1108 (Del. 1991), for example, the Delaware Supreme Court ruled that it was not neglectful for parents to refuse chemotherapy treatment for their three-year-old child, who suffered from "an aggressive and advanced form of pediatric cancer," because the proposed treatment was "highly invasive, painful, involved terrible temporary and potentially permanent side effects, posed an unacceptably low chance of success, and a high risk that the treatment itself would cause his death." *Id.* at 1109–10, 1118.

119. Andrews, *supra* note 2, at 60.

120. *See* Harrell, *supra* note 38, at 847 ("Given such real life consequences of a false positive and that the rate of false positives to true positives is as high as 10 to 1 (or higher) for many of the newborn screens . . . .").

relational, and even physical harms from follow-up testing and/or treatment.[121] While the magnitude of such harms is lower than failing to detect the condition, the probability of such harms is likely much greater than the probability of identifying the conditions screened for.

Despite these concerns and a general presumption against compulsory genetic screening in virtually every other context, mandatory NBS remains the norm, even when opportunities arise to change the nature of this institution.[122] As I argue in Part III, it may be time to rethink the role of consent in NBS, particularly with the potential of NBS to expand even further and as NBS samples are used more widely in research, as the next section shows. In addition, consent requirements may go far in promoting the NBS education that parents, providers, and scholars believe is woefully inadequate.[123]

### B. STORAGE AND SECONDARY USES OF NBS SAMPLES

Once the newborn blood spots are analyzed for the various NBS conditions, residual blood remains in the form of DBS.[124] Increasingly, states retain these samples for future uses, although the retention time varies significantly from state to state. Some states have provisions to retain samples for only one to four weeks, some for months, some for years, some for decades, and others indefinitely.[125] Often these samples are stored with identifying information.[126]

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121. *See id.* at 847–48.

122. MICH. COMM'N ON GENETIC PRIVACY & PROGRESS, FINAL REPORT AND RECOMMENDATIONS 4, 33 (1999). This Author was a member of the Michigan Commission on Genetic Privacy and Progress. Despite many months of deliberation, a majority of the committee voted to retain mandatory NBS, with an opt-out provision, although efforts were made to ensure that parents were to receive information about NBS.

123. Sandra J. Carnahan, *Biobanking Newborn Bloodspots for Genetic Research Without Consent*, 14 J. HEALTH CARE L. & POL'Y 299, 303, 322–25 (2011) ("Although educational pamphlets about the screening program are typically distributed to the parent, guardian, or managing conservator . . . state statutes, almost universally, do not require NBS programs to obtain the informed consent of the newborn's parent prior to extracting the blood sample.").

124. *Id.* at 301.

125. *See* Michelle H. Lewis et al., *State Laws Regarding the Retention and Use of Residual Newborn Screening Samples*, 127 PEDIATRICS 703, 704 (2011) ("A total of 40% of state public health laboratories have reported retaining DBS for at least 1 year."); Richard S. Olney et al., *Storage and Use of Residual Dried*

Although the samples are analyzed right away for NBS, there are several reasons states might want to retain the samples for months or even years. Many of these reasons are related to the underlying purpose of NBS. For example, the retention of these samples—along with contact information—is necessary for follow-up and to ensure that there will be appropriate intervention for an affected child.[127] In addition, labs may need to perform repeat tests to make a confirmatory diagnosis or to reassure families if there is a false positive.[128] Less directly related to NBS testing per se, but still connected to the public health aspects of NBS, is the retention of blood spots for quality assurance testing and to monitor the prevalence of various conditions in the state.[129] NBS samples may also be helpful for post-mortem diagnosis; for example, when trying to establish whether a genetic condition was related to a child's death.[130]

Increasingly, states are interested in long-term retention of these blood spots for purposes not directly related to NBS. Some states and/or other countries retain neonate blood spots for non-medical or non-research uses, such as identification in kidnappings or deaths.[131] NBS samples have also been used for paternity testing[132] and could potentially be used for the identification of criminals.[133]

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*Blood Spots from State Newborn Screening Programs*, 148 J. PEDIATRICS 618, 619 fig. (2006).

126. Carnahan, *supra* note 123, at 320 (observing that a 2002 study found that thirty-four out of thirty-six NBS program studies stored the DBS with identifying information).

127. *Id.* at 304.

128. NBSTF, *supra* note 28, at 414.

129. *Id.* at 404, 413, 415–16 (suggesting that knowing about the prevalence of various conditions is important not only for better understanding of the condition, but also for determining the optimal allocation of resources).

130. Linda Kharaboyan et al., *Storing Newborn Blood Spots: Modern Controversies*, 32 J.L. MED. & ETHICS 741, 742 (2004).

131. MICH. COMM'N ON GENETIC PRIVACY & PROGRESS, *supra* note 122, at 28.

132. In New Zealand, the High Court ordered the Auckland Health Services to provide the blood sample of a man's child for paternity testing that he sought after the baby died. *H v G* [M/1686/98] 1999, *upheld in H v G* (1999) 18 FRNZ 572 (HC).

133. Some have called for universal DNA databanking for criminal forensic purposes. *See, e.g.*, D.H. Kaye & Michael E. Smith, *DNA Databases for Law Enforcement: The Coverage Question and the Case for a Population-Wide Database*, *in* DNA AND THE CRIMINAL JUSTICE SYSTEM: THE TECHNOLOGY OF

In addition, these blood spots, like most pathology samples, are a treasure trove for researchers because they are a valuable national repository of genetic material. As genetic technology develops,[134] the blood spots are an especially rich source of research material: they are stable over time, they constitute an unbiased collection of samples since they represent the entire population,[135] and they can potentially be linked to basic demographic information.[136] As one author notes, "[n]ewborn screening initially began as a population health endeavor but is rapidly becoming a resource for population research."[137] Newborn blood samples have been used in research and shared with investigators since the 1980s,[138] sometimes with identifying information.[139]

Only recently have professional groups begun to consider seriously how to handle the problems of storage and secondary uses of the samples.[140] Very few states have specific regulations

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JUSTICE 247, 269–71 (David Lazer ed., 2004) (arguing that universal DNA databases would eliminate the disproportionate minority representation in forensic databases). NBS blood spots would offer an easy way to achieve this goal.

134. "Optimal storage conditions" for these samples are less crucial for genetic analysis than for other kinds of biochemical analysis. NBSTF, *supra* note 28, at 415.

135. Nanette Elster, *Future Uses of Residual Newborn Blood Spots: Legal and Ethical Considerations*, 45 JURIMETRICS 179, 180 (2005); Kharaboyan et al., *supra* note 130, at 745.

136. NBSTF, *supra* note 28, at 415 (noting, however, that because these bloodspots "will not be linked to clinical data on the children" their "potential utility . . . will need to be carefully evaluated").

137. Elster, *supra* note 135, at 189.

138. *See Innocent Blood: Use of Newborn Heel Sticks Spurs Legal Challenges*, IRB ADVISOR (AHC Media, Atlanta, Ga.), Dec. 1, 2009 [hereinafter *Innocent Blood*] (noting that many states used them to determine things like the prevalence of HIV infections, prenatal exposure to heavy metals, frequencies of certain genes); Michelle Lore, *Is the Minnesota Department of Health Violating Privacy Laws*, MINN. LAW., Nov. 30, 2009 (stating that since the end of 2008, 52,519 NBS samples from the state of Minnesota had been used for research).

139. Elizabeth Cohen, *The Government Has Your Baby's DNA*, CNN (Feb. 4, 2010), http://www.cnn.com/2010/HEALTH/02/04/baby.dna.government/ (noting that a study in Minnesota found that "more than 20 scientific papers have been published in the United States since 2000 using newborn blood samples").

140. NBSTF, *supra* note 28, at 389 (recommending that each state develop and implement policies for retention of residual DBS, educate parents regarding the storage and uses, and develop model consent forms and information materials for parents); Brad Therrell et al., *Briefing Paper: Considerations and Recommendations for a National Policy Regarding the*

governing what kind of future uses the samples may be put to or requiring that parents be notified of or give consent for such uses.[141] North Dakota, for example, does not require specific consent, stores the samples indefinitely, and permits the use of samples for "'medical, psychological or sociological research.'"[142] Indeed, because many parents do not realize that their child has been screened for various diseases, they are unaware of the possibility that a blood sample from their newborn may be stored in state health departments for potentially long periods of time and possibly shared with others for uses unrelated to NBS.[143]

The laws in a few states are an exception to this rule. In May of 2009, while the first Texas lawsuit challenging the state's practice of storing and using newborn samples for undisclosed research was pending,[144] the Texas Legislature amended its NBS laws to require parents and guardians to be informed that samples were being collected and would be stored indefinitely for potential research purposes.[145] Parents, or children upon reaching adulthood, can now request to have the

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*Retention and Use of Dried Blood Spot Specimens After Newborn Screening*, RESOURCE REPOSITORY (Aug. 26, 2009), http://resourcerepository.org/documents/1681/briefingpaper:considerationsandrecommendationsforanationalpolicyregardingtheretentionanduseofdriedbloodspotspecimensafternewborns/; *see APHL Position/Policy Statement: Residual Newborn Screening (NBS) Specimens*, APHL (2005), http://www.aphl.org/policy/Documents/residual_newborn_screening_specimens.pdf (suggesting that retention of DBS is important for laboratory quality assurance practices and can also be useful for research among other things); *see also* AM. COLL. OF MED. GENETICS, STANDARDS AND GUIDELINES FOR CLINICAL GENETIC LABORATORIES (2008) (finding it critical, if states do not retain DBS, for parents to have the option to have their children's DBS included in a national repository).

141. Lewis et al., *supra* note 125, at 703, 705, 707 (providing that "thirteen states specify the purposes for which DBS may be used," eight states require parents to be notified of the retention of DBS, and three require "parents to be informed" so that they can request destruction of the DBS). The United States is not the only country where samples are also stored for long periods of time. *See* Kharaboyan et al., *supra* note 130, at 742–43 (describing practices in Australia, Canada, Denmark, France, New Zealand, and the United Kingdom).

142. Whelan, *supra* note 18, at 428.

143. *See generally* TEX. HEALTH & SAFETY CODE ANN. §§ 33.0111–.0112 (West 2010) (showing the ability of a state to carry out such activities with DBS).

144. *See supra* note 18 and accompanying text.

145. *See* Higgins v. Tex. Dep't of Health Servs., 801 F. Supp. 2d 541, 544–45 (W.D. Tex. 2011).

samples destroyed within sixty days[146]—essentially an opt-out-of-research approach. The lawsuit was settled once the State of Texas agreed to destroy over five million coded newborn samples,[147] which had been stored indefinitely for possible research without parental consent.[148]

Minnesota also has a limited opt-out provision, allowing parents to refuse NBS itself or to request the destruction of test results and samples following screening.[149] Even so, the Minnesota Supreme Court ruled in favor of parents who sued the state for storing and authorizing public health research on newborn samples on the grounds that these practices violated Minnesota's genetic privacy law.[150] Although the court construed the NBS statutes to be "an express exception to the Genetic Privacy Act," the storage, dissemination, and use of the samples were not expressly authorized and therefore violated the privacy statute.[151] As a result of this decision, NBS samples in Minnesota were not available for research or public health studies. Recently, however, the Minnesota House of Representatives and the Minnesota Senate passed bills that would change this. If these bills become law, NBS samples would be available for research, unless parents or the child,

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146. *Id.* at 545.

147. Mary Ann Roser, *Samples of Newborns' Blood to Be Destroyed*, AUSTIN AM. STATESMAN, Dec. 23, 2009, at A1 (providing that the state decided that trying to seek consent from all of those parents was a worse option than simply destroying all of the samples). The samples were not identifiable, but because they are coded, a link exists that could be used to identify the child. *Id.*

148. Cohen, *supra* note 139 (noting that in other states it may be very difficult to convince the state to destroy your baby's archived blood sample). A class action filed late 2010 in Texas, also alleging that the state had stored DBS for the purposes of undisclosed research, was dismissed as moot because there was no evidence that the parties' newborn samples were actually used or distributed for research. *Higgins*, 801 F. Supp. 2d at 545, 554.

149. MINN. STAT. § 144.125 (2012); Lore, *supra* note 138 (explaining that absent parents opting out, the NBS test results may become public health data). In Minnesota, for example, the department of health has a contract with the Mayo Clinic for analysis of NBS samples, which allows the Clinic to "keep the samples indefinitely if there is no request for their destruction." *Id.* The samples are not identifiable, although they are coded, and therefore could potentially be linked to the individual. Kharaboyan et al., *supra* note 130, at 744.

150. MINN. STAT. § 13.386 (2013); Bearder v. Minnesota, 806 N.W. 2d 766, 776 (Minn. 2011); Lore, *supra* note 138 (stating that Minnesota has been storing the samples since 1997); *Innocent Blood*, *supra* note 138.

151. *Bearder*, 806 N.W. 2d at 776.

over the age of eighteen, opt out, which they may do at any time.[152]

Oklahoma and Michigan require more than the right to opt out. The Oklahoma Legislature recently enacted a provision that requires "express parental consent" for storage, dissemination, and use of a newborn's DNA.[153] Michigan, after seeking input from researchers, ethicists, community groups, and the state health department's institutional review board, created a specific repository for future research that would require affirmative, informed consent from parents.[154] This approach keeps the research uses of newborn samples separate and distinct from NBS itself, which remains mandatory.[155]

As these lawsuits and this legislation suggest, many secondary uses of DBS raise ethical and even legal concerns, particularly when the uses are not related to the purposes for which the samples were originally collected.[156] Particularly salient are the threats to privacy and confidentiality.[157] In addition, questions of autonomy and research ethics come into play because the newborns potentially become research subjects via their Guthrie cards.[158] Contemporary practices with NBS raise pressing questions as to whether consent must be secured for storage and secondary uses of NBS samples, and if so what kind of consent—general consent for research, or specific, informed consent for a particular use.[159]

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152. *Minnesota House Passes Newborn Screening Bill*, GENOME WEB (May 2, 2014), http://www.genomeweb.com/clinical-genomics/minnesota-house-passes-newborn-screening-bill.

153. OKLA. STAT. ANN. tit. 21, § 1175 (West 2012).

154. *Innocent Blood*, *supra* note 138; *see also* Denise Chrysler et al., *The Michigan BioTrust for Health: Using Dried Bloodspots for Research to Benefit the Community While Respecting the Individual*, 39 J.L. MED. & ETHICS 98, 98–99 (2011) (discussing the creation of Michigan's Neonatal Biobank).

155. MICH. COMP. LAWS ANN. § 333.5431 (West 2001).

156. *Innocent Blood*, *supra* note 138.

157. *Id.*

158. *Id.*; *see also* AGR, *supra* note 8, at 65 (discussing Guthrie cards).

159. These issues also tap into a longstanding debate about ownership and control over one's biological material, an issue on which we still have no clear consensus. Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 803–11 (2004); *see* C. Thomas, *The Use and Control of Heel Prick Blood Samples*, 24 MED. & L. 259, 261–68 (2005) (applying various theories of property ownership to NBS samples).

An important consideration in evaluating the propriety of the long-term storage and future uses of NBS samples is whether the samples are identifiable; that is to say, whether they can be linked directly to the newborn through identifying information or indirectly through a code. NBS blood spots must, of course, be identifiable initially so labs can locate and offer follow-up testing to children with abnormal results. But researchers try to anonymize previously identifiable samples by unlinking them from their source.[160] While some of the possible future uses of newborn samples require the samples to be identifiable—e.g., post-mortem identification, paternity testing, forensics, and future diagnostics—many kinds of research samples might potentially be anonymized, although as I note below, people are increasingly skeptical about the effectiveness of this practice.[161]

Current regulations require informed consent for research on biospecimens that have already been archived and are identifiable or linkable.[162] The Federal Protections for Human Research Subjects, sometimes called the "Common Rule,"[163] require documented informed consent for participation in research.[164] Research on *identifiable* DBS easily falls within the definition of human subject research under the regulations, which includes analysis of "identifiable private information."[165] While state NBS programs have "not traditionally been viewed as subject" to the Common Rule given that they are regulated by state health departments,[166] some scholars argue convincingly that the federal regulations should apply to research on DBS.[167]

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160. NBSTF, *supra* note 28, at 416 (noting that they may have been originally collected without identifiers or with identifiers that have been removed).

161. *Id.* at 416–17; *see infra* text accompanying note 220.

162. Carnahan, *supra* note 123, at 315.

163. *Id.* Seventeen federal agencies have adopted these protections "verbatim." *Id.* at 315 n.102.

164. 45 C.F.R. § 46.117 (2013); *see also* Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936.

165. 45 C.F.R. § 46.102(f) (2013) (defining human subject).

166. Carnahan, *supra* note 123, at 315–16.

167. *Id.* at 316–17 (arguing that federal dollars and policy guidance directly and indirectly support NBS, including the collection, analysis, and storage of "newborn bloodspots for future research purposes"); *e.g.*, Therrell et al., *supra* note 140, at 1, 3.

Under the existing regulations, however, research on de-identified biological samples is generally understood to be exempt from federal protections of human subjects research.[168] Indeed, the Office of Human Research Protections does not "consider research involving *only* coded private information or specimens to involve human subjects . . . if . . . the private information or specimens were not collected specifically for the currently proposed research project . . . and the investigator(s) cannot readily ascertain the identity to the individual(s) to whom the coded private information or specimens pertain."[169] One scholar argues that this exemption does not apply to DBS because they were collected not only as part of a screening program, but also as part of a "*research* program."[170] While sympathetic to the view that the exemption should not apply, I am not persuaded that these samples would be treated differently from any other biospecimens under the research regulations because these samples were not collected with any specific research protocol in mind.

The question of whether and how research should be allowed on NBS or other biosamples reflects tensions between public and private interests, and more specifically between norms that focus on the value of research and norms that focus on individual rights, autonomy, and privacy interests.[171]

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168. 45 C.F.R. § 46.101(b)(4) (2013) (exempting from the research regulations research "involving the collection or study of existing data . . . pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects").

169. U.S. Dep't of Health & Human Servs., OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens (2008), *available at* http://www.hhs.gov/ohrp/policy/cdebiol.html. This interpretation clearly seems to view research on biobanks with coded samples as not involving human subjects research, even though "[t]he increase in genomic data, as well as the increase of computerization of other records about individuals, will only make identifying 'anonymous' biobank files easier and easier." Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 352–55 (2007).

170. Carnahan, *supra* note 123, at 320 (observing that "one purpose" of the collection and storage of the DBS "is for *future* genetic research").

171. Storage of Genetics Materials Comm., Am. Coll. of Med. Genetics, *ACMG Statement: Statement on Storage and Use of Genetic Materials*, 57 AM. J. HUM. GENETICS 1499 (1995). This issue creates tension between the ethical principle of informed consent, which argues in favor of recontacting individuals to obtain their consent, and the serious impracticabilities of doing so.

Similar tensions about autonomy interests versus some conception of the public good arise with respect to the question of whether consent should be required for NBS itself.[172] In trying to determine how best to resolve these tensions, Part III sets up a framework for balancing the conflicting interests and applies this approach to the specific questions of whether some form of consent should be required for: 1) the storage and research uses of NBS samples; and 2) some or all aspects of NBS itself.

## III. BALANCING THE INTERESTS

In exploring the tensions between the public good and the individual's privacy and autonomy interests, we can see how biases can influence the weight of the interests.[173] As we shall see below, those who strongly promote research and its benefits to newborns and society tend to undervalue the privacy and autonomy interests at stake. Similarly, the strong proponents of privacy and autonomy tend to undervalue the public value of the long-term retention and research use of DBS. As a result, they reach an impasse, not only because they value things differently, but also because their approaches differ.

Many proponents of expansive access to NBS samples and other archived tissues "tend to rely on a narrow version of consequentialism" to justify a broad range of research practices, while minimizing the privacy and autonomy interests at stake.[174] The benefits of this approach seem "concrete and tangible"[175]: preventing morbidity and mortality in newborns, and gaining knowledge about various inherited disorders to advance medicine and clinical care.[176] The risks of broader access to NBS samples—privacy intrusions and the loss of autonomy interests—"are more amorphous concerns and are therefore less viscerally compelling."[177] Indeed, many of the public benefit proponents easily dismiss the value of autonomy

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172. *See* Suter, *supra* note 50, at 246–50 (discussing value considerations in prenatal testing).

173. Sonia M. Suter, *All in the Family: Privacy and DNA Familial Searching*, 23 HARV. J.L. & TECH. 309, 375–76 (2010) [hereinafter Suter, *AITF*] (discussing a parallel trend with DNA familial searches).

174. *Id.*

175. *Id.*

176. Carnahan, *supra* note 123, at 300.

177. Suter, *AITF*, *supra* note 173, at 375.

and privacy, and informed consent.[178] This view argues for expansive NBS with mandatory testing, long-term retention of samples, and broad access to these samples by researchers without consent.

In contrast, a position that privileges privacy and autonomy would push toward requiring detailed informed consent for all aspects of NBS: the collection of samples, the subsequent analysis, the retention of samples, the manner in which they are stored (coded, identifiable, or anonymized), access to the samples, and uses to which the samples are put.[179] This approach would limit many of the potential research benefits that have come from NBS programs and use of the samples.[180]

Clearly neither extreme fully considers all that is at stake. As a result, I recommend an approach that "does not focus exclusively on one or just a few values or desirable consequences. Instead, it recognizes the competing goods at stake."[181] Because I have described this approach in more detail in an earlier piece, I will only briefly outline the methodology, which borrows from philosopher W.D. Ross.[182] The central premise is that we have various underlying prima facie duties, which may sometimes come into conflict.[183] We have, for example, prima facie duties to protect the public by supporting and encouraging research and identifying children with treatable conditions in a timely manner to minimize morbidity and mortality. We also have prima facie duties to protect the autonomy of the family and the future autonomy of the newborns with respect to medical decision making and participation in research, and duties to protect the privacy of newborns. None of these duties is absolute in the sense that they must always override conflicting duties.[184] Instead, all of these duties are "intrinsically binding"—they hold sway over us, but "they are not always determinative of how we should act in

178. *Id.* at 376.
179. Carnahan, *supra* note 123, at 322–25.
180. *Id.* at 322 (noting that informed consent is problematic because future research methods are unknowable).
181. Suter, *AITF*, *supra* note 173, at 376.
182. *Id.*
183. *Id.* at 376–77.
184. *Id.* at 377.

any given instance . . . . Instead we can only determine what our actual duty is in any circumstance by full reflection."[185]

This approach does not attempt to declare winners and losers when competing values come into play. Rather, it attempts to reach a resolution that may ultimately tip more in the direction of one duty than the other, but which continues to recognize the pull of the competing values.[186] That is to say, when we determine what the actual duty is in any particular circumstance, we should not abandon or forget about the overridden prima facie obligations, because they continue to "exert force on our subsequent attitudes and actions"[187] and leave "residual effects" or "moral traces."[188] If our full reflection leads us to decide that certain research goals are particularly important to society, we may decide to limit autonomy to some extent to allow for that research. The pull of our duty to protect individual autonomy, however, continues to compel us to "approximate as closely as possible the values enshrined in the overridden duty" so that we develop measures that least infringe on parental autonomy.[189]

Considering whether consent should be required in NBS forces us to make difficult choices between various competing values and find ways to give weight, as much as possible, to the overridden prima facie duties. In particular, we must apply this balancing approach to decide: 1) what kind of consent provisions, if any, we should use for NBS itself; and 2) whether

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185. *Id.* I note in this piece that "this methodology does not offer conclusive answers to most moral questions." *Id.* at 378. It is, nevertheless, not arbitrary or subjective. Rather, it requires a kind of "reflective equilibrium" where we "check decisions from general principles against more intuitive judgments about proper outcomes for particular cases." *Id.* at 379. *See generally* JOHN RAWLS, A THEORY OF JUSTICE 15–19, 40–47 (rev. ed. 1999) (describing the "reflective equilibrium").

186. Suter, *AITF*, *supra* note 173, at 378.

187. *Id.*

188. JAMES F. CHILDRESS, MORAL RESPONSIBILITY IN CONFLICTS: ESSAYS ON NONVIOLENCE, WAR, AND CONSCIENCE 69 (1982) (citing Robert Nozick, *Moral Complications and Moral Structures*, 13 NAT. L.F. 1 (1968)); RICHARD B. MILLER, CASUISTRY AND MODERN ETHICS: A POETICS OF PRACTICAL REASONING 47 (1996); Suter, *AITF*, *supra* note 173, at 376 ("[O]verridden values remain significant and continue to exert force and obligations on our actions and deliberations. In other words, the overridden values do not go away; they retain 'moral traces.'").

189. MILLER, *supra* note 188, at 47.

consent should be required, and if so what kind, for the storage and future uses of the samples.

I should emphasize that the issue of consent for NBS itself and consent for storage and future uses need not be treated as a package. Indeed, there are strong arguments for separating the process of screening from the process of the creation of biobanks, as I suggest below, and therefore completely disaggregating the questions of consent. At the moment, however, affirmative consent is generally removed from the entire process. When we disaggregate the two sets of decisions—whether to participate in NBS and whether to participate in the biobank—it becomes clear that the conflicting public/private values are very different. With respect to NBS itself, at least when the conditions screened for develop in infancy and are treatable or subject to amelioration, the conflict is between the state's interest in the well-being of the newborn and the autonomy of the family. With respect to questions of storage and, in particular, research uses of the samples, the public value of research comes into conflict with the private values of the families' autonomy interests and the newborn's privacy and future autonomy interests. Because each set of questions raises different tensions, I address each issue in turn. I begin with the research question because it has received the most attention recently and because it indirectly has implications for the question of consent for NBS itself.

### A. RETENTION AND RESEARCH USES OF DBS

In only a few other contexts does the government take one's tissue samples without consent and retain them for extended periods of time: after conviction of certain crimes,[190] and in the military.[191] In the first instance, the conviction results in the loss of certain liberty interests.[192] And in the case of the military, one has a choice not to join the military. But in the context of NBS, samples are usually taken without parental consent and then stored for long periods, potentially to be used

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190. Bonnie L. Taylor, Comment, *Storing DNA Samples of Non-Convicted Persons & the Debate over DNA Database Expansion*, 20 T.M. COOLEY L. REV. 509, 512–14 (2003).

191. Megan Allyse et al., *Ethics Watch: The G.I. Genome: Ethical Implications of Genome Sequencing in the Military*, 12 NATURE REVIEWS GENETICS 589 (2011).

192. Taylor, *supra* note 190, at 514.

for research, an approach that "veers from the norm."[193] As noted, the justifications for doing so in the case of NBS are rooted in a perspective that emphasizes the value of research and that views archived samples as something akin to community property.[194] Some also argue that the public interest and value of research are not just communal interests, but also individual interests because everyone benefits from the research.[195]

Even if we value research, however, we must recognize the competing interests in autonomy and privacy in being able to decide whether and to what extent to participate in research and to control access to personal information. Privacy advocates point out the dignitary interests, sometimes suggesting that biosamples belong to the individual.[196] Serious privacy concerns arise when others have access to our genetic material, which contains "a wealth of personal information such as predisposition to certain diseases, behaviors, physical and mental traits, parentage, and genetic relatedness to others."[197] The fact that the DBS contains genetic information and is likely to be "readily identifiable" leads some to say that consent is

193. Cohen, *supra* note 139.

194. *See* David Korn, *Genetic Privacy, Medical Information Privacy, and the Use of Human Tissue Specimens in Research*, *in* GENETIC TESTING AND THE USE OF INFORMATION 16, 53 (Clarisa Long ed., 1999) (arguing that archived human tissues are "a public resource dedicated to the public good, not, like a savings bank, a depository of private property"); *see also* Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr. 16, 2006, at M45 ("[P]eople are morally obligated to allow their bits and pieces to be used to advance knowledge to help others. Since everybody benefits, everybody can accept the small risks of having their tissue scraps used in research." (quoting David Korn, *supra*)).

195. Korn, *supra* note 194, at 60; Karen Rothenberg, *The Social Implications of the Use of Stored Tissue Samples: Context, Control, and Community*, *in* GENETIC TESTING AND THE USE OF INFORMATION 84, 85–88 (Clarisa Long ed., 1999) (suggesting that both privacy and research are public and private interests); *see also* Lisa Feuchtbaum et al., *Questioning the Need for Informed Consent: A Case Study of California's Experience with a Pilot Newborn Screening Research Project*, 2 J. EMPIRICAL RES. ON HUM. RES. ETHICS 3, 3 (2007) ("[T]he legitimate needs of society and the interests of newborns should not be sacrificed to respond to the autonomy interests of the few parents who did not wish their infant to participate in the study . . . .").

196. Andrews, *supra* note 2, at 63.

197. Suter, *AITF*, *supra* note 173, at 331.

required whether or not the samples are "linked or linkable."[198] Because this information is "fundamental and basic to our makeup" and plays such "an important, though not monolithic, role in influencing our 'temperament, health, capacities, and physical appearance,'"[199] legislators at the state and federal level have enacted various forms of genetic privacy protections in the last few decades.[200] I, like many others, have argued that genetic information is "integral to the self," and therefore is among the kinds of personal information in which we have strong privacy interests.[201]

Proponents of consent provisions for research on biosamples are also motivated by a commitment to principles of autonomy; the notion that individuals may not be treated as merely a means to an end.[202] Indeed, these ethical principles have led not only to formal declarations about the various ways in which researchers have an ethical obligation to protect research subjects, but also to legal regulations protecting the way in which research may and may not be conducted in the United States.[203] Among the most fundamental principles of these ethical and legal norms are informed consent and the idea that the researchers have a fiduciary obligation to protect research subjects. A decision to become a participant in research either to advance medicine or to benefit others and/or oneself is a self-defining decision. It also creates a relationship of trust because it involves sharing personal information with researchers, imposing on them "special duties of care because of the imbalance of power inherent in the relationship."[204]

The degree to which we emphasize our duties to promote research or to protect autonomy and privacy will determine our

198. Katherine Drabiak-Syed, *Legal Regulation of Banking Newborn Blood Spots for Research: How* Bearder *and* Beleno *Resolved the Question of Consent*, 11 HOUS. J. HEALTH L. & POL'Y 1, 13 (2011).

199. Suter, *AITF*, *supra* note 173, at 332.

200. *See, e.g.*, Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, 122 Stat. 881; *Genetic Privacy Laws*, NAT'L CONF. ST. LEGISLATURES, http://www.ncsl.org/default.aspx?tabid=14287 (last updated Jan. 2008) (describing the full range of state genetic privacy laws).

201. Suter, *supra* note 159, at 773. I have also noted that "genetic information is not uniquely, nor is all genetic information equally, central to the conception of the self." Suter, *AITF*, *supra* note 173, at 334.

202. FURROW ET AL., *supra* note 107, at 405.

203. *See* 45 C.F.R. §§ 46.301–.306 (2013) (otherwise known as the "Common Rule").

204. Suter, *supra* note 159, at 787.

approach to research on DBS. Under the extreme pro-research position, samples should be available in any form for use by researchers for any kind of investigation. Such an approach would seriously undermine the privacy interests of the child and autonomy interests of the family. It would allow the use of the newborn samples in identifiable form, which would privilege research over privacy and autonomy. Not surprisingly, this approach is inconsistent with the well-established consensus that under the Common Rule, identifiable samples cannot be used for research without one's informed consent.[205] The Common Rule recognizes that the value of research, while real, is not absolute and therefore cannot override autonomy at all costs.[206]

At the other, pro-privacy/autonomy extreme, any future use of the samples for research would require detailed informed consent whether the samples were identifiable, coded, or anonymized, regardless of the uses. This approach would privilege privacy and autonomy interests over the value to the public of various research studies, potentially hindering research. It would be extremely difficult (if not impossible) and expensive to implement since it would require researchers to locate families to seek their consent for virtually every future study. Moreover, meaningful informed consent is often impossible to obtain when biospecimens, whether DBS or other forms, are initially collected because the parents or sources of the samples cannot be informed of all possible research uses and outcomes. In some ways, it might even be counter-productive to privacy interests since it would require the samples to remain identifiable while in long-term storage for the purpose of contacting the families.

The current system and recommended approach of some scholars and professional groups might be considered a compromise of sorts; informed consent is required if the samples are identifiable, but otherwise consent is not required for

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205. 45 C.F.R. §§ 46.101(b)(4), 46.111(a)(4) (2013).

206. There are many methodologically sound and highly valuable types of research that we do not allow because values like privacy, autonomy, and the mental and physical well-being of individuals would make such studies unethical. The unfortunate history of human subject research in Nazi Germany and even in this country has taught us important lessons about the limits to which we can endanger others and limit their autonomy simply to further science. FURROW ET AL., *supra* note 107, at 405–13.

anonymized or de-identified samples.[207] The theory, in brief, is that the privacy risks are substantially minimized once identifiers are removed. To the extent that no samples are ever truly anonymized, however, this argument becomes less persuasive. In addition, as some have pointed out, even under this system, sometimes researchers actually use biospecimens with identifiers, rather than in anonymized form, without obtaining consent or Institutional Review Board (IRB) approval.[208]

Regardless of whether we consider the current system appropriate for biobanks in general, we must recognize that NBS biobanks are unique in implicating particularly salient privacy and autonomy interests. First, parents often have not given consent to (or are even aware of) the collection of the biospecimen and NBS in the first place, let alone the long-term storage and potential research on the specimens. Indeed, one study showed that only twelve states mention specimen storage in the informational pamphlet that parents receive for NBS.[209] With other biobanks, it is likely that the source of the specimen consented to (and knew about) the removal of the sample from his or her body (whether or not consent was given for later uses of the sample).

Second, these samples are obtained from minors and therefore any research on these samples is research on children, who are treated under the Common Rule as a vulnerable class deserving of heightened protection.[210] While minors can participate in research, there are very limited instances in

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207. Amy L. McGuire & Laura M. Beskow, *Informed Consent in Genomics and Genetic Research*, 11 ANN. REV. GENOMICS & HUM. GENETICS 361, 370 (2010).

208. Drabiak-Syed, *supra* note 198, at 43. When the plaintiff in the *Bearder* litigation requested documentation from the Minnesota Department of Health (MDH) regarding its process of de-identification of samples for research, the MDH stated that it had no such documents, suggesting that "there is no established de-identification procedure and that the process and standards vary from project to project and are subject to subjective standards." Whelan, *supra* note 18, at 441 (internal quotation marks omitted).

209. SEC'YS ADVISORY COMM. ON HERITABLE DISORDERS IN NEWBORNS & CHILDREN, CONSIDERATIONS AND RECOMMENDATIONS FOR NATIONAL GUIDANCE REGARDING THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING 16 (2009) [hereinafter ACHDNC] (citing personal communication with Aaron Goldenberg).

210. *See* 45 C.F.R. §§ 46.401–.409 (2013) (describing "Additional Protections for Children Involved as Research Subjects").

which consent for participation is not required. For example, even the least problematic category of research on children—"[r]esearch not involving greater than minimal risk"—still requires the child's assent and parental consent,[211] unless the general waiver provisions for informed consent apply.[212] Scholars have debated whether the waiver provisions should apply in this context.[213] The crux of the matter turns on whether informed consent is practicable or not. As one scholar notes, even when researchers do not have to obtain informed consent under the regulations, they often do, demonstrating that it is not always impracticable.[214] When children are involved and their biospecimens are retained for long periods of time, there is a strong argument that they should have the right (upon reaching the age of majority) to decide for themselves whether they want to be research participants.[215]

Third, as I shall argue in more detail below, the state, as protector of the newborn and as mandator of the collection of the DBS, has a fiduciary obligation to protect the autonomy and privacy interests of the newborn with respect to the collection, retention, and use of the samples. For all of these reasons, whatever concerns we may have about the use of biobanks without consent (informed or general) are further heightened in this context.

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211. 45 C.F.R. § 46.404.

212. 45 C.F.R. § 46.116(d) (2013) (waiving informed consent requirements when the research "involves no more than minimal risk to the subjects . . . [t]he waiver or alteration will not adversely affect the rights and welfare of the subjects . . . [t]he research could not practicably be carried out without the waiver or alteration," and when appropriate, "the subjects will be provided with additional pertinent information after participation").

213. *Compare* ACHDNC, *supra* note 209, at 19 ("A balanced consideration of concerns justifies waiving informed consent for population-based newborn screening research using de-identified specimens when a clinically well-defined test and an effective therapy are present."), *with* Carnahan, *supra* note 123, at 320–21 (challenging the notion that informed consent would be "impracticable" because "a physician-patient relationship already exists between the physician and the mother-to-be, and it is typically the physician that is responsible for obtaining the bloodspot for screening and research"), *and* Drabiak-Syed, *supra* note 198, at 38 (suggesting that waiver has "been used as a creative mechanism to overcome administrative barriers").

214. Ellen Wright Clayton, *Patients and Biobanks*, 51 VILL. L. REV. 793, 796–97 (2006).

215. David Gurwitz et al., *Children and Population Biobanks*, 325 SCI. 818, 818 (2009).

As a result, we should not weigh the interest in favor of research as strongly in this context as we might with respect to other types of biobanks. Indeed, this strongly supports the view that we should prohibit the use of DBS for any research.[216] While this would certainly limit the privacy and autonomy risks for the newborn and his or her family, to the extent that this population offers unique possibilities for research, one might argue that such a proposal goes too far. It is undoubtedly true that much of the research done on DBS need not be done on that particular population. But some forms of research may benefit substantially by collecting data from a pool, like the NBS samples, which represents the population so well. In addition, to the extent that any clinical data are combined with research on the DBS, research from birth through later life might offer unique insights into various disease processes that would be harder to obtain with other populations. Given that research of these samples poses heightened concerns, however, if any research on DBS should be allowed, it should be limited to research that benefits the pediatric population. Michigan's approach, for example, recognizes the importance of using newborn samples only for research that is relevant to the pediatric community.[217]

To the extent that any research goes forward on DBS, for all of the reasons described above, it is appropriate to give families (and the child upon reaching the age of majority) some control over whether the DBS are archived for research purposes. Consistent with current requirements for research on biospecimens, informed consent should be obtained for research on identifiable NBS samples generally (except in the rare instances where a waiver could apply).

Under the current interpretations of the Common Rule, however, affirmative consent would not be required for de-identified samples,[218] which is problematic in the NBS context. As biobanks generally become more prevalent and central to genomics research, scholars have debated whether this approach is ethically justifiable, not just with respect to NBS, but for all biobanks. Scholars have argued that "a person has an

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216. Hank Greely has argued that there is simply no reason for researchers to utilize DBS when there are other biorepositories to use. Author's personal communication.

217. Chrysler et al., *supra* note 154, at 99.

218. McGuire & Beskow, *supra* note 207, at 370.

interest in consenting or not consenting to be part of research," even if it includes analysis of biospecimens.[219] Growing concerns about the inability to truly anonymize biological samples[220] have led to further calls to rethink the current approach toward research on biospecimens.[221] Indeed, in response to advances "in genetic and information technologies that make complete de-identification of biospecimens impossible," the Department of Health and Human Services proposed changes to the consent requirements for research on biospecimens.[222] Specifically, the proposed changes would eliminate the ability to do research on de-identified biological samples without consent. Instead, it would require "written *general* consent" for research use of archival biospecimens, whether or not researchers ultimately decide to use identifiers.[223] The intended general written consent would allow individuals "to say no to all future research," and give them the option to say yes or no to "a handful of special categories of research with biospecimens" that might raise "unique concerns . . . for a significant segment of the public."[224] In addition, the proposed changes would allow

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219. *See, e.g.*, Greely, *supra* note 169, at 356.

220. *See, e.g.*, *id.* at 351–52; Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321, 321 (2013); Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, 4 PUB. LIBR. SCI. GENETICS, Aug. 29, 2008, at 1–2; Zhen Lin et al., *Genomic Research and Human Subject Privacy*, 305 SCI. 183, 183 (2004); Amy L. McGuire & Richard A. Gibbs, *No Longer De-Identified*, 312 SCI. 370, 370–71 (2006); Laura L. Rodriguez et al., *The Complexities of Genomic Identifiability*, 339 SCI. 275, 275–76 (2013).

221. *See, e.g.*, Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED & ETHICS 22, 24 (2005); Carnahan, *supra* note 123, at 320.

222. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,525 (proposed July 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, 164). These were part of a broader proposed overhaul of the "Common Rule." *Id.* at 44,514.

223. *Id.* at 44,519 (emphasis added). The proposed regulations would move away from the concept of "exempt research" and create a new category of "excused research" that is intended both to "increase protections"—by requiring general consent as opposed to no consent for all biospecimens (as well as for pre-existing data collected for research, whether or not the researcher uses identifiers, and for pre-existing data that were collected for purposes other than research, if the researcher uses identifiers)—"and broaden the types of studies covered," by allowing researchers to use identified biospecimens as long as they had general consent. *Id.* at 44,518–19.

224. *Id.* at 44,519–20 (giving as examples the creation of cell lines or reproductive research).

for waivers in some (unspecified) instances.[225] Although these proposed regulations have not been adopted so far, they reflect an attempt to balance the pressures to promote research and protect individual privacy and autonomy.[226]

Following a modified version of the proposed amendments to the regulations for human subjects research, states should ask for *general* consent for the storage of DBS for future research uses of de-identified DBS.[227] Parents would be entitled to say no to all future research, yes to all future research, or no to a handful of specific categories of research that might be problematic.[228] In addition, children, upon reaching the age of majority, should be able to refuse consent for research or for particular categories of research.[229]

The focus on general, as opposed to detailed informed, consent serves two functions. It attempts to give parents (and the future adult the newborn will become) some autonomy protections while recognizing the value of research.[230] It concedes the pro-research view that fully informed consent in this context truly is problematic; at the time the samples are collected, there may not be any specific plans for research, let alone for specific research protocols.[231] Thus, it is simply impossible to inform parents about the details of possible future research. In addition, the circumstances in which the samples are collected—during the newborn period—do not easily lend themselves to the lengthy discussions that informed consent

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225. The advance notice of proposed rulemaking (ANPRM), however, notes that the waivers "would not necessarily be the same as those for other types of research." *Id.* at 44,520.

226. *Id.*

227. *Id.* at 44,519. I call this a modified version because the ANPRM would require general consent for both the use of identified and identifiable samples. In my view, as long as informed consent is required for identifiable samples in other contexts, there is no argument for affording NBS biobanks less protection than other biobanks. Moreover, the rationale for using samples in this form would likely be to follow clinical outcomes, which itself would require considerable efforts to contact families or physicians to obtain clinical information.

228. *Id.* at 44,518–20.

229. *Id.* at 44,524.

230. Feuchtbaum et al., *supra* note 195, at 8–9 (discussing parental autonomy protections).

231. Elster, *supra* note 135, at 187–88.

would require, even if the specific future research protocols were known.[232]

Of course, if we were to separate the NBS process from the collection of samples for research, then this removes many of the challenges of obtaining consent during the newborn period. Such an approach might be justified by the concerns that the research is not in any one newborn's best interest, but instead serves the public good.[233] As a result, we should eliminate any pressure to consent to research that might occur during the newborn period, especially if parents do not fully understand that the question of screening is not conceptually or practically linked to whether or not research is done.

But disaggregating consent for screening from consent for research does not eliminate the general problem of obtaining fully informed consent for research on pathology samples, given the impossibility of knowing about all future research endeavors in advance. Moreover, such disaggregation potentially removes one of the benefits of collecting DBS during the newborn period—the potential of collecting samples that represent the population. The challenges of tracking down families after that period would undoubtedly diminish the yield of samples available for research, potentially even more than the process of trying to obtain more complete informed consent. A lesser, but real, concern is that families that wanted to support such research but were not tracked down would lose out on the chance to consent to research. Of course, seeking consent for retention of samples for research in the prenatal period might lessen these concerns, although this would not be helpful in cases where women do not receive prenatal care.[234] Thus, while some powerful reasons argue for separating consent for research from consent for NBS, we should recognize that such an approach is not without costs.

At whatever stage the consent process occurs for research on DBS, I am advocating what is essentially an opt-in approach for future research. Undoubtedly, even this approach would be less favorable to the research community than being able to access de-identified samples without any consent requirement,

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232. *Id.*

233. Drabiak-Syed, *supra* note 198, at 36–38 (focusing on the benefit of the majority).

234. Whelan, *supra* note 18, at 452 (noting that not all women receive prenatal care).

because surely the latter approach would maximize the number of available samples. As a second choice, they would likely prefer opt-out to opt-in provisions under the theory that they are likely to have a larger pool of samples if parents must act affirmatively to *prevent* the storage of the samples, as opposed to requiring parents' affirmative consent *for* storage and future research.[235] One consideration in choosing opt-in versus opt-out approaches is what the legislative default goals are. If the incentives are to promote research, the "nudging" of an opt-out approach may be viewed as making it more likely that such samples are available.[236] But given the many concerns surrounding research on DBS, it is hard to argue we should be trying to "nudge" families into participating in research.

In fact, the data so far suggest that it is debatable how great the risk is that people would decline participation in research. Several studies suggest that a large percentage of parents would consent to participate in research.[237] A 2008 study, for example, found that 90% of mothers would agree to participate in an NBS biobank with no restrictions on the type of research performed.[238] Another study found that 76.2% of parents were "very or somewhat willing" to permit storage of and research on DBS, whereas if consent were not obtained, only 28.2% would be "very or somewhat willing" to allow the use of DBS for research.[239] On the other hand, Texas's limited experience with opt-out provisions suggests that it had some, though not a significant, effect on the size of the newborn pool. In a roughly six-month period, 240,000 samples were collected

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235. *Innocent Blood*, *supra* note 138 (explaining how any samples moving forward require consent as part of the opt-in program).

236. *See* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS 83–86 (2008) (noting the importance of the default position for opt-out v. opt-in rules).

237. *E.g.*, Feuchtbaum et al., *supra* note 195, at 7–8; Alon B. Neidich et al., *Empirical Data About Women's Attitudes Towards a Hypothetical Pediatric Biobank*, 146A AM. J. MED. GENETICS 297, 299 (2008); B.A. Tarini et al., *Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research*, 13 PUB. HEALTH GENOMICS 125, 130 (2010).

238. Neidich et al., *supra* note 237, at 302; *see also* Feuchtbaum et al., *supra* note 195, at 7 (stating that although not all parents were asked to participate in a study of NBS because of the burdens on the hospital, ninety percent of those asked consented to enroll their NBS in the study to research NBS testing methods and to identify additional genetic diseases).

239. Tarini et al., *supra* note 237, at 128–29 (finding that women had misperceptions about what participation in a biobank would entail).

and the state received 6900 requests to destroy samples—a rate of 2.8%.[240] We do not know how these numbers would compare with an opt-in provision or what parents understood about storage and possible future uses when they opted out.

In addition, there are potentially legitimate concerns about the possibility of consent bias when parents opt in. Many argue that giving people the opportunity to say no would not only reduce the pool of biospecimens available for research because of "uninformed denial,"[241] but would also lead to consent bias in the biospecimens that are available.[242] Given that the pool of newborns is so vast, there may be reason to think that the effects of consent bias might be lessened, albeit not completely eliminated, by the sheer number of samples potentially available.

Even if evidence shows that the pool of research samples might be smaller with an opt-in provision or that there is a greater risk of consent bias, this alone is not a reason to reject these measures to protect autonomy.[243] The entire justification for removing consent requirements from NBS generally is the notion that the screening program is intended to benefit newborns.[244] Removing consent for participation in future research on DBS cannot be justified on the same grounds.[245] The extent to which the research benefits newborns may vary, but even research that is primarily geared toward benefiting newborns will provide much more indirect benefits than the actual screening for treatable and serious conditions.[246] Research that does not focus on the newborn or pediatric population offers even less benefit to newborns and cannot at all justify the lack of consent.[247] Thus, as noted earlier, any

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240. Roser, *supra* note 147, at A1.

241. Korn, *supra* note 194, at 48.

242. *E.g.*, Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 95–98 (2011); Kharaboyan et al., *supra* note 130, at 747.

243. Drabiak-Syed, *supra* note 198, at 36 (noting that the "benefit to the majority is not alone a sufficient interest to override individual autonomy"); Whelan, *supra* note 18, at 453 ("As a society, we cannot allow administrative costs or burdens to justify infringements on individual rights, parental rights, and genetic privacy.").

244. Drabiak-Syed, *supra* note 198, at 36.

245. *Innocent Blood*, *supra* note 138.

246. Feuchtbaum et al., *supra* note 195, at 7–9.

247. *Id.* at 11–12.

research on DBS should ideally be limited to that which benefits the pediatric population.

One additional concern with the opt-in approach is that requiring affirmative consent for retention and research uses of DBS will lead some parents to opt out of NBS altogether in jurisdictions where that is possible.[248] Here, the value of providing parental autonomy and the child's future autonomy is set against the potential harms to newborns if severe and treatable conditions are not identified in the newborn period.[249] This concern might, therefore, argue for decoupling consent for NBS from the consent for research uses of DBS.

There is a strong argument to be made the other way, however. Whether or not the consent process for NBS and research are disaggregated, seeking parental consent for future research on the DBS helps establish the public's trust in the NBS process generally.[250] Recent attention to long-term storage and research uses of these samples may lead parents to think of NBS, not so much as a program intended to protect the health of newborns, but as an effort to create a universal research pool.[251] This may create push back with respect to NBS altogether, causing parents to opt out of NBS to resist what they perceive as the heavy hand of government.[252] As Dr. Jeffery Botkin suggests, denying parents the chance to opt out of future research may undermine the public's trust in the entire endeavor.[253] Indeed, it is precisely such suspicion and loss of trust that led to the lawsuits in Texas and Minnesota.[254] As one parent in the Texas lawsuit explained, "To me, this whole thing is about consent . . . . If they had asked me I probably would have consented. The fact that it was a secret program really made me so suspicious of the true motives, there's no way I would consent now."[255] Thus, as long as any research is done on the DBS, whether consent is obtained in the future or during the newborn period, the public needs to know

248. *Id.* at 11.
249. *Id.* at 8–9.
250. Drabiak-Syed, *supra* note 184, at 12–13, 23, 42.
251. *Id.* at 23, 35–36.
252. *Id.* at 35–36.
253. *Innocent Blood*, *supra* note 138 (quoting Jeffrey R. Boktin).
254. Drabiak-Syed, *supra* note 198, at 25–34.
255. Roser, *supra* note 147, at A1; *see also* Whelan, *supra* note 18, at 442 ("As one parent succinctly stated: 'I want to have the choice.'").

that any use of these samples requires affirmative consent from parents. The state should not *presume* consent.

Not only is the public's trust important to the sustainability of the NBS project as a whole, but trust is also inherent in the relationship the state creates between itself and the child in setting up NBS. The most persuasive justification for NBS is the *parens patriae* notion that the state steps in to act as parent for the child.[256] This creates a trust-based, fiduciary relationship (which goes beyond the ordinary fiduciary obligation the state owes its citizens) given that the state takes over some aspects of the child's care for the well-being of the child.[257] As a consequence, a strong obligation exists not only to ensure that NBS maximizes the well-being of the child, but to ensure that any ancillary uses of the samples do not in any way undermine the best interests of the child, even for the benefit of society as a whole.

Michigan's creation of the BioTrust for Health, which is intended to facilitate and promote research on the DBS of NBS, was modeled on the concept of a charitable trust.[258] Under this model, the source of the specimen (in this case the parent acting on behalf of the child) "formally expresses" the desire to transfer the specimen into the control of the trustee (the state) who will keep the sample for the benefit of the beneficiary (the general public).[259] Important to this approach is the notion that the transfer is *intentional and freely given*, and that the recipient of biospecimens (in this case the state) "has a responsibility to serve as a trustee, or steward, of the tissue to ensure protection of the contribution."[260] This model suggests three things: first, that parents should consent to the use of their newborn's samples for inclusion in the research biobank; second, that the samples are to be used for the benefit of the public; and third, and most important, that the recipient has a fiduciary obligation not only to develop clear rules about the kinds of uses to which these samples can be put, but also to implement security measures to protect the confidentiality of the

256. AGR, *supra* note 8, at 261.

257. *Id.*

258. Chrysler et al., *supra* note 154, at 98 (citing David J. Winickoff & Richard Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENG. J. MED. 1180, 1180 (2003)).

259. Winickoff & Winickoff, *supra* note 258, at 1182–83.

260. *Id.* at 1182.

information in the samples.[261] Given the limits of de-identification and anonymization in protecting privacy,[262] it is particularly important that the state develop explicit guidelines as to the legitimate uses of the samples both in terms of the best interests of the newborns and the public and in terms of security measures.

Indeed, the charitable trust model does not require that the state hold the DBS. Instead, a non-state charitable trust could be created and charged with the obligation of holding the samples and ensuring that their use is for the benefit of the public. The fact that the state would not possess the DBS and that this approach would disentangle the NBS process from the research aspects would likely help promote public trust.

While there are legitimate concerns about the impracticabilities of obtaining informed consent about future research uses, efforts should be made to inform parents about the general nature of the permissible and impermissible uses of the samples as well as security provisions. Such efforts would not only protect the autonomy interests of the family, but might also indirectly promote research. If families believe that the government has given careful attention to the kinds of uses that it will and will not allow, and has been attentive to the security of this personal information, families may be more inclined to participate. Otherwise, the public may not trust the state, believing, at best, that it has been negligent in protecting against problematic uses of the samples or, at worst, that the state may have malignant plans for such samples, which is why it has not set limits on these future uses.

### B. CONSENT FOR NBS ITSELF

A conclusion that parental consent should be required for storage and research use of a newborn's DBS does not necessarily mean that consent should also be required for NBS itself. In fact, Michigan, whose BioTrust approach for research on DBS is commendable, requires written consent for the inclusion of the samples in the biobank (and the right of a child upon age of majority to have their DBS removed), but it does

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261. *See id.* at 1182–83 (describing the charitable trust model generally and emphasizing the factors asserted in the text).

262. Greely, *supra* note 169, at 352–55.

not require consent for the screening.[263] Moreover, the balance of public and private interests argues less strongly for affirmative consent with respect to NBS than in the research context since achieving high rates of NBS not only benefits the newborn, but also parents and society as a whole.[264] Even though I concede that the case for consent is less strong in this context, the recent and likely future expansions in NBS make an increasingly compelling case for rethinking parental consent in this context as well.[265]

To be sure, there are serious challenges in requiring true informed consent for the screening itself. Given the number of diseases screened for, obtaining meaningful informed consent of the sort that the law demands for a physically invasive and risky medical procedure would be virtually impossible for each and every condition in the NBS panel.[266] The likely expansion of the panel of diseases and possibility of whole genome sequencing in the future only enhances this problem. Whatever challenges conveying this wealth of information presents in ordinary circumstances are magnified by the fact that the disclosures typically occur during the newborn period, when parents are unlikely to be able to process the details of the nature of each of these conditions, the various treatment options for affected children, and the likelihood each of the conditions will manifest symptoms.[267] Additional concerns surrounding informed consent are the economic and logistical

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263. Chrysler et al., *supra* note 154, at 100.

264. Feuchtbaum et al., *supra* note 195, at 8–12.

265. Even if consent should occur for NBS, however, it does not follow that it should occur at the same time as consent for research. Indeed, as noted above, there are some powerful reasons to separate out the two consent processes.

266. This is a problem generally with any kind of multiplex testing. *See, e.g.*, Council on Ethical & Judicial Affairs, Am. Med. Ass'n, *Multiplex Genetic Testing*, HASTINGS CENTER REP., July–Aug. 1998, at 15, 15–18 (explaining multiplex genetic testing and informed consent within this context); Robert J. Wells, Correspondence, *Generic Consent for Genetic Screening*, 331 NEW ENG. J. MED. 1024, 1024 (1994) ("Burdening us all with a system of 'enforceable' standards . . . will keep us ignorant by delaying the gathering of information needed to make these kinds of determinations."); *see also* Greely, *supra* note 169, at 352–55, 357–59 (discussing the hurdles in obtaining informed consent for genetic research and testing).

267. AGR, *supra* note 8, at 6 (explaining the disclosure methods during the newborn period).

burdens such a requirement would place on health care providers and the public health system.[268]

How logistically challenging it is to obtain consent for NBS, however, is debatable. One much cited pilot study for a new NBS technology confirms some of these worries. The research study, which required informed consent, found that obtaining written informed consent was a "serious logistical burden" for the hospitals involved.[269] As a result, the researchers only achieved forty-seven percent participation in the study.[270] On the other hand, a study in Germany suggested that much higher participation rates could be achieved when written consent was sought.[271] In that case, almost ninety-nine percent of the parents consented to NBS.[272] Similarly, an older study of Maryland's previous informed consent approach to NBS found "no evidence that the parental consent regulation had a negative effect on the public's health. . . . [or] that the [NBS] program had become less cost-effective."[273] The data seems mixed as to the burden that seeking informed or written consent imposes.

To say, however, that obtaining true informed consent is impossible, results in unacceptably low yields of parental consent, or is effective but unduly expensive, does not mean we should abandon all efforts to seek *any* form of parental consent.[274] An approach that requires affirmative parental consent—i.e., an opt-in approach—would offer the next best form of respecting parental autonomy. Most states, however, have chosen the opt-out approach, which theoretically still offers some parental control because it creates the right for parents who greatly oppose NBS to decline screening of their

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268. *Id.* at 156–57.

269. Feuchtbaum et al., *supra* note 195, at 6.

270. *See id.* at 7 (stating that only forty-seven percent of newborns participated in the MS/MS screening during the pilot study's time frame).

271. Bernhard Liebl et al., *Very High Compliance in an Expanded MS-MS-Based Newborn Screening Program Despite Written Parental Consent*, 34 PREVENTIVE MED. 127, 127 (2002).

272. *Id.* at 127, 130–31.

273. Faden et al., *supra* note 80, at 1351.

274. *See* Ainsley Newson, *Should Parental Refusals of Newborn Screening Be Respected?*, 15 CAMBRIDGE Q. HEALTHCARE ETHICS 135, 140, 144 (2006) ("Although parental autonomy is not, of course, legally or morally limitless, parents should (and do) enjoy a degree of freedom from state interference in private and family life.").

newborn.[275] In order for an opt-out option to offer any true semblance of respecting parental autonomy, however, parents must understand that they have an option to opt out, which requires some awareness and general understanding of the NBS process and the option to opt out.[276] Unfortunately, that rarely happens.[277] This may be because providers fail to inform parents, because so much is happening during the newborn period that parents cannot absorb or process whatever information they might get, or some combination of the two. As a result, there is a strong case for NBS education to occur in the prenatal period when there is more time for reflection, discussion, and comprehension.[278] Although, again, this is only helpful for women who receive prenatal care.

Even if education regarding NBS were enhanced by requiring NBS education during the prenatal period, there is reason to think that an opt-out approach would still be less than optimal if the goal is parental education. The incentives simply are too few to educate parents under an opt-out as compared to an opt-in approach. Under an opt-out approach, the default is to test, which creates no incentive to discuss NBS with parents.[279] Testing will occur with or without such a discussion. A statutory requirement to discuss NBS might not be a sufficient incentive to educate the families in light of the many other demands on health care providers' time. In contrast, under an opt-in approach, the default is not to test unless parents consent, which creates strong incentives to discuss NBS with parents, even if only in general terms.[280]

An additional argument in favor of the opt-in approach, given the goal of parental education, is that it is more cost-

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275. Feuchtbaum et al., *supra* note 195, at 9.

276. Moody & Choudhry, *supra* note 9, at 246–48.

277. *See id.* at 240, 244 (noting that parents "are not even aware that they have a clear choice to make" in the United Kingdom's opt-out program, and finding in their own study that 41.7% of respondents "did not feel able to decline," while many thought NBS was "compulsory").

278. *See, e.g.*, MICH. DEP'T OF CMTY. HEALTH, NEWBORN SCREENING GUIDE FOR HOSPITALS 19 (2014) ("Education is ideally done during the prenatal period.").

279. Faden et al., *supra* note 80, at 1350 (discussing how mothers believe a routine default procedure does not require consent or discussion).

280. *Id.* at 1351 (describing the procedure in Maryland, which would appear to be similar to the current suggestion).

effective than full-blown informed consent would be.[281] The study of Maryland's program established, albeit many years ago, that parents can be educated adequately about newborn screening *generally*—not with respect to the details of every condition—in no more than five minutes.[282] Further, there are cost-effective methods, such as decision aids, which are being developed for a range of medical decisions,[283] to provide parents with an overview of NBS. Indeed, some have advocated a system that would provide basic information about NBS to parents with options for access to more detailed information should they want it.[284] Such an approach would further promote autonomy by allowing people to decide how much information to receive.

Were there evidence to suggest that an opt-in approach would lead to a great deal of uninformed denial, this might be a powerful reason to forgo some protections of parental autonomy to prevent (the admittedly small number of) newborns from suffering from debilitating or life-threatening illnesses. But evidence suggests, as we shall see, that involving parents in the decision-making process may actually *enhance* the effectiveness of NBS, and therefore opt-in provisions may further both goals—protecting the health of the newborn population and promoting parental autonomy.[285]

A study conducted over two decades ago showed that the refusal rate for NBS is really quite low in the states where NBS is truly voluntary.[286] It found that Maryland and New Hampshire, out of twelve states studied, had the highest percentage of NBS: ninety-eight percent of their newborns.[287]

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281. *See id.* ("There was also no evidence that the program had become less cost-effective because of increased costs to the health care system.").

282. *See id.* at 1350 ("Most nurses . . . responded that obtaining consent or refusal took from one to five minutes.").

283. *See, e.g.*, Elie A. Akl et al., *A Decision Aid for COPD Patients Considering Inhaled Steroid Therapy: Development and Before and After Pilot Testing*, BMC MED. INFORMATICS & DECISION MAKING, May 15, 2007, at 1, 4–6 (discussing the use of decision aids for COPD).

284. Harrell, *supra* note 38, at 849–50.

285. Jean-Louis Dhondt, *Implementation of Informed Consent for a Cystic Fibrosis Newborn Screening Program in France: Low Refusal Rates for Optional Testing*, 147 J. PEDIATRICS S106, S107–08 (Supp. Sept. 2005); Liebl et al., *supra* note 271, at 130–31.

286. Andrews, *supra* note 2, at 60.

287. *Id.*

Maryland had a program that required informed consent[288] (it now has an opt-out approach[289]), and New Hampshire allows parents to refuse NBS for any reason.[290] In contrast, the other ten states, all with mandatory screening programs that allow parental refusal only for religious reasons, screened fewer newborns. One state managed to screen a mere fifty-eight percent of its neonates.[291] More recent studies show that parental consent is over ninety percent when parents are allowed to opt out of screening or even sometimes required to consent affirmatively.[292] A possible explanation for these data is that a voluntary program that informs and educates parents about NBS induces parents to ensure actively that their children will actually get screened.[293] By contrast, mandatory programs—especially those in which parents are not well-educated about NBS—lack this additional "check on the procedure," resulting in a lower yield of children screened.[294]

Interestingly, most parents do not believe that informed, or sometimes even *any*, parental consent is necessary for NBS,[295] at least with respect to conditions that present in infancy. On first glance, these findings might cut in favor of maintaining the status quo. In one study, parents did, however, want choice.[296] Nearly three-quarters of parents preferred opting out and a

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288. PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 45.

289. MD. CODE ANN., HEALTH–GEN. § 13-109 (West 2013).

290. N.H. REV. STAT. ANN. § 132:10-c (2013).

291. Andrews, *supra* note 2, at 60–61. This study did not investigate an important question, which is how effective the education efforts are in these, as opposed to other, opt-out programs.

292. Dhondt, *supra* note 285, at S106; Liebl et al., *supra* note 271, at 130–31; Evelyn P. Parsons et al., *Mothers' Accounts of Screening Newborn Babies in Wales (UK)*, 23 MIDWIFERY 59, 62–63 (2007).

293. Liebl et al., *supra* note 271, at 130–31. One author questions whether the "consent" procedures in these voluntary programs are truly informed because consent is given at the time of screening. She suggests that parents will say yes to anything right after birth, which could result in artificially high consent rates and could explain why the voluntary programs have such high participation rates. Harrell, *supra* note 38, at 850.

294. Andrews, *supra* note 2, at 60.

295. Elizabeth D. Campbell & Lainie Friedman Ross, *Incorporating Newborn Screening into Prenatal Care*, 190 AM. J. OBSTETRICS & GYNECOLOGY 876, 876–77 (2004); Faden et al., *supra* note 80, at 1350–51 (stating that forty-six percent felt that their consent should not be sought); Moody & Choudhry, *supra* note 9, at 246–48.

296. Moody & Choudhry, *supra* note 9, at 244–46.

little over one-quarter preferred opt-in approaches.[297] However, when asked about mandatory screening for conditions that do not present in infancy, such as Duchenne muscular dystrophy, which presents between three and ten years of age, and Alzheimer's disease, which presents in adulthood, a majority of parents opposed mandatory screening.[298] This may reflect the fact that there is little that can be done to prevent these conditions from developing in the newborn period or at all. On the other hand, another study found that most parents support mandatory screening of diseases that present in infancy, even if no treatment is available,[299] suggesting that for some parents elimination of the diagnostic odyssey, even if nothing can be done, is important for childhood illnesses.

The fact that parents are not clamoring to give consent for NBS or that they seem to prefer opt-out over opt-in approaches, ironically, may support an opt-in approach. The typical reason for their views is a concern that other parents would not consent. This supports the findings that when consent is required, there is actually a high level of acquiescence.[300] In other words, the majority of parents would likely consent to NBS themselves; they do not want consent requirements because they fear that *other* parents would not consent. This reasoning alone does not, of course, necessarily overcome the concerns of cost, time, and logistical demands associated with affirmative consent.[301]

What further argues in favor of the opt-in approach is the fact that parents consistently express a strong desire for *education* and *information* regarding NBS, which they are not getting.[302] Overall, studies suggest that parents "were more troubled over the lack of NBS education than by the lack of

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297. *Id.* at 246.

298. L.E. Hasegawa et al., *Parental Attitudes Toward Ethical and Social Issues Surrounding the Expansion of Newborn Screening Using New Technologies*, 14 PUB. HEALTH GENOMICS 298, 303 (2011); *see also* Campbell & Ross, *supra* note 295, at 876–77.

299. Hasegawa et al., *supra* note 298, at 303–04.

300. *See supra* notes 286–94 and accompanying text.

301. *See* Elster, *supra* note 135, at 187–89 (discussing the ethical and legal issues regarding informed consent).

302. TIMMERMANS & BUCHBINDER, *supra* note 8, at 61 ("Public opinion research suggests that few new parents know about newborn screening."); Hasegawa et al., *supra* note 298, at 302. *But see* Whelan, *supra* note 18, at 428 ("[A] majority of parents are aware of the initial screening.").

consent."[303] Many urge that such education should happen in the less hectic prenatal, as opposed to newborn, period when they would be less preoccupied.[304] If the goal is primarily to satisfy parental requests for information, it may be that requiring affirmative consent is the best way to do that. Studies have shown that seeking affirmative consent can increase parental knowledge in the context of research studies.[305] In addition, as noted above, the incentives to provide some information about NBS are greater with an opt-in as compared with an opt-out approach. Thus, a powerful justification for requiring opt-in for NBS itself is to enhance the chances that parents understand something about NBS, which can satisfy their desires and likely promote the effectiveness of NBS.

If we could trust that the education would happen in the prenatal, or even newborn, period, the case for opting in would be weaker. The current inadequacy of parental education, however, not only supports the opt-in requirement as a method to try to ensure that such education occurs;[306] it is relevant in another respect. An opt-out approach is only protective of autonomous decision making it if is *informed* refusal.[307] If parents are not adequately educated about NBS, or even worse that NBS occurs and that they can refuse, the opt-out approach makes a mockery of the notion of autonomous decision making and informed refusal. Instead, it merely leaves parents with an empty legal right to refuse. Even if most parents, when educated about NBS, would choose not to opt out, many who do not opt out are not making an affirmative choice because they

303. Hasegawa et al., *supra* note 297, at 303; *see also* NEDRA S. WHITEHEAD ET AL., DEVELOPING A CONJOINT ANALYSIS SURVEY OF PARENTAL ATTITUDES REGARDING VOLUNTARY NEWBORN SCREENING 6 (2010), *available at* http://www.rti.org/pubs/mr-0014-1003-whitehead.pdf ("Most parents would like more information on newborn screening . . . ."); Campbell & Ross, *supra* note 295, at 877 (examining the need for increased prenatal NBS education); Faden et al., *supra* note 80, at 1350 (providing that around eighty percent wanted to be informed that NBS was done).

304. WHITEHEAD ET AL., *supra* note 303, at 6; Campbell & Ross, *supra* note 295, at 877.

305. Neil A. Holtzman et al., *Effect of Parental Informed Consent on Mothers' Knowledge of Newborn Screening*, 72 PEDIATRICS 807, 811 (1983); Parsons et al., *supra* note 292, at 63–65.

306. Campbell & Ross, *supra* note 295, at 877 (discussing how parents are strongly requesting the necessary education, especially during the prenatal period).

307. Newson, *supra* note 274, at 141 (showing how an informed decision to refuse consent does not override autonomy).

did not know about NBS or the opportunity to opt out.[308] In short, the opt-out approach under the current circumstances is so far from true consent or informed decision making that it is hard to argue that it does anything at all to promote autonomy.[309]

If providers were to offer the kind of information about NBS that would make the opt-out approach truly informed refusal, the process would be quite close to informed *consent*. At that point, the distinctions between opt-out and opt-in are simply not that great. Indeed, studies show that if individuals are adequately informed, the number who opt in is the inverse of those who opt out.[310] One of the reasons for the opt-out is the idea of "nudging" people to make the "right" choices.[311] Given that the parent community is, based both on parents' views and surveys of parents' choices, not a community that needs to be nudged with respect to NBS, and given the added incentives to educate parents that opt-ins provide, the case of opt-in over opt-out becomes greater.

While there has been a long tradition opposing an opt-in approach, the reasons for reconsidering this approach are quickly growing.[312] First, the fact that the broader panel of diseases increases the risks of false positives or the possibility of incidental findings of uncertain clinical relevance means that some of the psychosocial risks of NBS are increasing.[313] Parental awareness of NBS may prepare parents for and therefore decrease the anxiety and confusion associated with false positives and diagnostically ambiguous results, for example.[314] Parents who understand in advance that NBS is merely a *screening*, and not a diagnostic, procedure and that a positive result is not determinative are less likely to experience

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308. *Innocent Blood*, *supra* note 138 (explaining that without the proper education the parents are not truly given the option to opt out).

309. Whelan, *supra* note 18, at 448 (describing opt-out programs as "'not a true model of consent'" but as a mere "'substitute for consent'").

310. Liebl et al., *supra* note 271, at 127 (specifying that lack of knowledge was a significant barrier to providing consent).

311. Feuchtbaum et al., *supra* note 195, at 8–10 (discussing the positive effect of having the option to opt out).

312. *Cf. id.* at 9 (most states favor the opt-out approach).

313. *See* Fyrö & Bodegård, *supra* note 59, at 107, 111 (noting the "persistent anxiety" associated with false positives); *supra* text accompanying notes 58–72.

314. *See* WHITEHEAD ET AL., *supra* note 303, at 14–19 (describing the anxiety and depression felt by parents following a false positive).

anxiety with respect to a false positive than parents who did not even know their child was screened.[315] To the extent that an opt-in approach promotes parents' awareness of NBS, this approach might function, in part, as a prophylactic to this concern.

Second, as the panel of diseases screened for expands to include diseases for which there is limited or no ameliorative treatment in the newborn period, the rationale for testing without consent disappears. The entire justification for screening without consent is the idea that the state is protecting newborns from suffering the harms of treatable conditions, which is not true with untreatable conditions.[316] In this instance, as with storing and doing research on DBS, the *parens patriae* notion used to justify screening treatable conditions without consent does not exist. As a result, the argument for affirmative consent in these cases becomes significantly stronger.

The fact that there is serious consideration of including whole genome or exome sequencing in NBS[317] should give us even more reason to be skeptical of opt-out approaches, for both of the reasons discussed above. Whatever concerns we might have about expanded panels of NBS with respect to false positives, incidental and ambiguous findings, and information about conditions for which there is no treatment are bound to be magnified considerably by the sheer amount of information that whole genome/exome sequencing (WG/ES) can generate. Indeed, for that reason, there is a very strong case to be made against nudging parents toward consent for WG/ES NBS and a very strong argument for giving parents affirmative choice—i.e., the opt-in approach.

Even if one were to argue that opt-outs are important to "nudge" parents into consenting to testing for serious, treatable conditions, as states expand their NBS panels to include conditions for which there are no treatments or WG/ES, this rationale cannot apply to the full range of screening. Rather than use an opt-out approach for all of the NBS, it would be preferable to tier the decision-making process so that there is only an option to opt out of screening for treatable conditions,

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315. *See id.* at 19 (explaining that information reduced this stress).

316. *See* Faden et al., *supra* note 80, at 1350–51 (discussing the support of parents who believe consent is not necessary for routine testing).

317. *See supra* notes 52–54 and accompanying text.

and perhaps only for those that express in childhood. Parents, however, would have to opt in for the rest. Of course, for the reasons I gave above, I believe opt-in for all NBS is preferable. Moreover, the administrative difficulties of setting up two consent approaches for different types of diseases further argues for a single approach, in this case, opt-in.[318] But given the strong impetus in favor of opt-out for treatable conditions, it seems extremely important to ensure that consent is *affirmative*, and not presumed, when it comes to conditions for which there is no treatment, especially if they are late-onset conditions.

Finally, my arguments for seeking affirmative consent for the storage and future use of the DBS offer a final reason to advocate for opt-in approaches to NBS generally. Efforts to seek consent for research and storage of samples would effectively necessitate a discussion about NBS generally. It is only a minimal extra step to seek consent for the screening itself. Some might argue that each new decision that parents are confronted with or asked to make complicates and slows down the overall process. It seems difficult, however, to discuss the collection, storage, and research use of DBS without first explaining NBS and its purpose, at least in general terms. Given that parental awareness of NBS is likely to promote successful NBS, and given that parents want to be educated about the program, the general discussions about NBS that an affirmative consent rule would require seem very much in line with what would be required for a discussion of storage and research uses. As a result, promoting parental awareness of NBS through affirmative consent seems well worth the time. While this might not satisfy the notion of fully informed consent, it might achieve the best compromise between parental autonomy and the common good. It fulfills our prima facie duties to promote individual autonomy, while also honoring our prima facie duties as a society to protect the physical welfare of newborns by informing parents about NBS generally and seeking, rather than simply presuming, their affirmative consent.

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318. Feuchtbaum et al., *supra* note 195, at 10–11.

## CONCLUSION

As I have argued, the dignitary principle of respect that is central to autonomy and consent should remain central to all aspects of the NBS program from the moment the samples are collected to the moment the state considers using the samples. While autonomy should not be the overriding principle in determining what approach to take, there is a risk in deciding that the state's interest in helping newborns and advancing science will run roughshod over the family's autonomy interests and the child's privacy and future autonomy interests in determining the extent to which he or she wants to participate in research. As we have seen, many of the public goods may actually be advanced by approaches that recognize the value of autonomy and privacy, with appropriate limits, so as not to hinder the ability to protect newborns or engage in certain valuable research projects.

Underlying the goal of achieving the appropriate balance between the public good and individual interests is a third consideration: the need for transparency when the government has control over samples with highly personal information. Whatever balance of autonomy and promotion of research governments choose, they owe a fiduciary obligation to the citizenry to act not only for the benefit of the public, but to assure there is public authorization and transparency. The public's trust in the government is at stake in the development of NBS research programs.[319] This argues for educating the public not only about the existing NBS policies, but also about new approaches the state is considering so that the public may share in deliberations over the delicate balance between the public and private interests. To quote John Rawls, it is essential for a "well-ordered society" to resolve such difficult matters based on "the ideals and principles expressed by society's conception of political justice, and *conducted open to view on that basis*."[320] Until the government does a better job of educating parents about the full spectrum of issues and decisions it has made with respect to NBS, this will not be possible. This article is a call to the states to ensure that they move toward such openness.

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319. *See supra* notes 249–56 and accompanying text.

320. JOHN RAWLS, POLITICAL LIBERALISM 213 (expanded ed. 2005) (emphasis added).

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 30

## Deposition of Dr. Antonio Yancey

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MICHIGAN

ADAM KANUSZEWSKI, et al,

Plaintiffs, Case No. 18-cv-10472

v

MICHIGAN DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

Defendant.

/

VIDEO CONFERENCE DEPOSITION OF ANTONIO YANCEY

Taken by the Plaintiffs on the 7th day of October, 2020, via Zoom, at 12:00 p.m.

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Via Zoom Video Conference

Wednesday, October 7, 2020 - At 12:02 p.m.

REPORTER: Do you solemnly swear or affirm that the testimony you're about to give shall be the whole truth?

DR. YANCEY: I do.

MR. ELLISON: Good morning, Doctor. My name is Attorney Phillip Ellison. I'm counsel for four parents and nine children in a case that's been brought in the Eastern District Court known as the Kanuszewski vs the Department of Health and Human Services case.

ANTONIO YANCEY

having been called by the Plaintiffs and sworn:

EXAMINATION

BY MR. ELLISON:

Q What I'm going -- today we're doing your deposition. Have you ever done a deposition before?

**A. I have.**

Q. You have. Okay. All right. Just know as a matter of practice that I'm a little more nonspecific than I sometimes try to be, so if my question is not clear in any way, you're not going to insult me or otherwise upset me in any way if you say, "Phil, that doesn't make sense. Can you ask it another way?" or "Try again." Okay? So feel free to jump in if it doesn't make sense, all right?

**A. Okay.**

Q. What I'm going to do today, do you have access -- I mean, I can see you on the screen right now. I'm going to show some documents on a computer screen. Do you have the ability to see those? I know I see a light that's pretty bright behind you there, but can you see the screen okay if I were to share a document?

**A. Yeah, I see them.**

Q. Okay. Fair enough. I don't need you to adjust, as long as you can see it. You're a little more of an outline because you're real bright behind you, but that's fine for me so it doesn't matter for me.

MR. KENNEDY: You've got a halo, Doctor.

THE WITNESS: I was just thinking that.

MR. ELLISON: Well, it's better than my horns that usually show up behind me here.

THE WITNESS: Right, right.

Q. Anyway, all right. Well, let's get started here then. Just for the record you are Dr. Antonio Yancey, correct?

**A. Correct.**

Q. All right. And you are -- and I'm just -- to make this quick, you're the director of the Michigan Neonatal Biobank, correct?

**A. Correct.**

Q. All right. How long have you served in that role as a director of the Biobank?

**A Since April of 2017.**

Q And what does that role consist of?

**A So I'm pretty much the -- I mean, I'm the director, so I'm responsible for the overall operations of the Biobank. I'm responsible for all of the financials for the Biobank, just pretty much what a typical director would do, just oversee operations and the finance. That includes logistical stuff in terms of building -- the building and assets that are in the lab, just typical things that a director would do.**

Q Sure. So you would be -- not to put words in your mouth, but you would be in charge of all of the personnel and equipment, and assets of the Biobank?

**A That's correct.**

Q All right. And as I understand it also, you serve in administration at Wayne State University as well?

**A Right. So I'm the associate vice president for research operations for Wayne State University. I'm actually a Wayne State University employee. I'm not employed by the Biobank and one of my responsibilities as the associate vice president for the Biobank -- I mean as the director, sorry --**

Q Take your time. Take your time. Not a problem.

**A Yeah. One of my responsibilities as the associate vice president of research operations is to manage the Biobank.**

Q Okay. Do you get any compensation from the Biobank as part

of your duties?

**A I do not.**

Q All right. Let me ask it this way: If you were to take a new position or retire today or decide, "I no longer want to be here in the lovely State of Michigan anymore" and you go somewhere else, the person it that would assume your role at Wayne State University would also assume the directorship of the Biobank?

**A That is correct. So there was a predecessor that worked for -- prior to me taking over, I think for at least the last ten years. This has always been set up that way here the individual that's managing the Biobank, they also have other responsibilities within a division of research, and it just varies on the position itself but again, I was put into the position in 2017 when my predecessor left the University.**

Q As part of this -- as part of your role with the Biobank, I've come to learn and maybe you can confirm for me that you're part of a board of directors with the Biobank, correct?

**A That's correct.**

Q All right. Just so we're clear for the record today, when I reference the Biobank, that's the shorthand version of what I'm referring to as the Michigan Neonatal Biobank, Inc. Fair enough?

**A That's correct.**

Q All right. I'm going to share my -- we're going to see if this works right now. I'm going to try to share my screen and we'll see if I can make this -- okay. Can you see on the screen right? You can see, well, your picture right there?

**A It's me.**

Q All right. Fantastic. This is a -- I'm just going to represent --

**A That's when I was younger.**

Q Well, I always joke I like the younger pictures of me. There's less facial real estate, as I tell people, right? So we all look better yesteryear, but let's blame COVID. We'll blame COVID for all of that, right?

**A. Right, right.**

Q Anyway, what I've been presented, just for the record, that this is what I presented to the witness as Exhibit M for purposes of this deposition.

(Deposition Exhibit M marked)

Q. Doctor, this is a -- and I'm just going to represent to you this is a printout of the board of directors page of the Michigan -- of the Biobank website. I see -- I'm going to present to you there's four -- excuse me. There's six photographs with six people identified. Are those the current members of the board of directors for the Biobank?

**A. That's correct.**

Q. All right. Do you know how they got their roles with the Biobank as on the board of directors?

**A. I do not.**

Q. I noticed looking at the sheet here with the six of you that you're the only one that's got the word "director" underneath that. What distinguishes you as a director versus the other five that are there in that capacity?

**A. So again, I'm the actual director of the Biobank, and so pretty much, again, I'm over -- I see over -- I see the operations for the Biobank, but I also have an appointment on the board too, and the rest of these individuals are strictly board members, so they don't have anything to do with the day-to-day operations where I do.**

Q Again, not to put words in your mouth, but you'd be like the manager, but you also have a participation on the board of directors as well, correct?

**A Correct. I'm the director of the Biobank, correct.**

Q Well, let me ask it this way: When there's a board meeting of the board of directors for the Biobank, you would participate in that board of directors meeting, correct?

**A That would be correct.**

Q All right. Do you have a vote? Well, let me lay a foundation. Does the board of directors vote on matters of Biobank concerns?

**A Yeah. They -- we do. I mean, it's more like -- pretty**

**much -- it's not anything formal, think. It's more discussion and collaborations with conversations and decisions of that sort, but I guess the answer would be yes.**

Q I'm going to ask it this way: I mean, one of the things -- my wife -- my wife is a school board president, right? So, you know, there is not, as you can imagine, a lot of hotly contested -- you know, like the Supreme Court is a 5-4 decision. Those thins are done by discussion. They reach a consensus at these board meetings, so long as there's no dissent. Is that -- would that be a fair characterization of how this board operates?

**A Correct.**

Q All right. And you would be a person that would participate and would try to reach a consensus with the other five members of the board for issues that come up that go before the board of directors?

**A No, that's not correct.**

Q That's not correct? Okay.

**A. I don't have -- yeah. I'm the secretary of the board, so my job pretty much is to facilitate the agendas and, you know, kind of organize the meetings, but I don't have a decision in any of the discussions at all.**

Q Okay. All right. Fair enough. And that's why we get these depositions, I get to learn such things. Okay. I guess what I want to start with -- I'm going to turn that -- let's

see here. Just to be clear, is there -- other than these six -- well, you identified the five board members plus you as the director. Is there anybody else that's involved with the board of directors for the Biobank?

**A In terms of board of directors?**

Q Yes.

**A No.**

Q I'm just going to leave -- I'll tell you what I'm going to do. I'm just going to leave that there, see if that works. Nope. I did that wrong. All right. So we'll jump back and forth a little bit here.

**A Okay.**

Q This is the new world order. I've done exactly three depositions by Zoom. We don't normally -- we always usually do these in person with printouts in front of everybody. What I want to kind of understand that you can help educate me and ultimately, through this deposition, the Court, is what is the nature of the role of the Biobank vis-a-vis Can you explain that?

**A Yeah. So the Biobank really in simple terms, is that we're just a depository, a storage area, so our job is to strictly store the blood spots. That's what we do.**

Q Okay. Well, what's -- now you guys are formulated as an independent -- legally -- I guess legally independent nonprofit corporation, correct?

**A Correct. We are a 501(c).**

Q. Okay. And hence why you have a board of directors?

**A. Correct.**

Q. Right. Let me ask this: Let's just pretend for the sake of argument that my son was born three years ago. His -- we'll get into how blood gets in in just a minute, but let's just assume for the sake of discussion that his blood spot is in your Biobank, okay? Can I just come to you guys and say, "Give me his blood sample back"?

**A. No, you cannot.**

Q. Okay. That's what I want to understand. What role do -- does the Biobank fulfill or operate under as it connects to the Michigan Department of Health and Human Services?

**A Okay. So our job is merely -- I'm going to probably say the word "storage" a lot, because that's what we are.**

Q Fair enough.

**A So basically, our relationship with the State is that we're basically just a storage facility, so what happens is is that any residual blood spots that are left from testing at the State lab, those are basically sent to the Biobank, to the operations that I manage, and then our job is to get those blood spots and we basically store them in our storage facility. That's pretty much what we do, so when those blood spots come, they come from the -- Lansing sends them to the State of Michigan building on West Grand Boulevard,**

**which is walking distance from our facility. We have an employed that picks up those and they're called the residuals, just leftover again from the State. My team picks up those blood spots and what we do is we catalog them into a system and then eventually from that system it goes into a storage facility that's temperature controlled. And so, we have no idea, you know, who the blood spots are. They come with us with I believe it's an eight-digit number, what's called like a -- it's an association with a Julian date, but there is no -- there is no information on that and our job is basically to store them in numerical order in terms of the Julian date and they go into our storage facility, so that's what we do.**

Q Okay. Let me ask this then. Why, if you know -- and, again I should be clear. I know you've done a deposition before. If you don't know the answer to a question, it's perfectly fine to tell me you don't know.

**A Okay.**

Q Do you know why you -- why the Biobank is structured as a nonprofit rather than simply the Department of Health and Human Services just simply having a cooler themselves or renting a facility themselves? Why do we need the Biobank?

**A I have no idea. That was probably way before my time. I never -- I don't know the answer to that.**

Q Okay. Now, in your role as director of the Biobank, I know

one of the allegations in this complaint that I've made against you is that you're acting either in concert with or are a state actor. I guess what I'm trying to understand is who -- I mean, you've talked about your board of directors this morning. Who is in charge over you in terms of the Biobank?

**A So I report -- well, I report to the -- it's kind of the way it's structured, because I'm a Wayne State employee I report to the vice president of research for Wayne State University. That's who I report to in terms of Wayne State. But then I also report to the board as a whole. So I have two -- you know, basically two supervisors, if you would, but primarily all of my evaluations, my performance is all done by the vice president for research for Wayne State University. There is no input or anything that goes to the VP of research in terms of my performance, so I really kind of really see myself I guess technically reporting to the vice president for research.**

Q When you say research, that would be at Wayne State University, correct?

**A. That is correct.**

Q. One of the things -- let me just say I'm sympathetic to what you're trying to articulate because I've been trying to sort out the legal structure of how things fit together, and just my statement, not whether you agree with it, but it's

complicated.

**A Right.**

Q Let me ask this question: One of the things that I've been trying to figure out is as I started -- kind of the top of this line of questions is assume I have my son's -- my son's blood sample is in your guys' Biobank, right? It's in one of the cards and as I've nicknamed them in my mind, the coolers, right? Temperature-controlled facilities, fair?

**A Right.**

Q Okay. And just let me tell you, I'm going to use probably the wrong words too when it comes to -- I'm not a science person, so if you need to correct me --

**A Right.**

Q -- please feel free.

**A. Okay.**

Q So I imagine these blood samples on these Guthrie cards that have been cut up into squares are in a cooler; would that be fair?

**A. Yes, it's fair.**

Q. Okay. And they're --

**A. Some are in -- let me clarify that. There are some that are in a cooler and some that are not in a cooler.**

Q. Okay.

**A. So some --**

Q. Let's get that -- I was going to ask about that, so let's

get that one out of the way. Why are some of these in coolers and why are some of them at ambient temperatures?

**A So at some point -- and I can't -- this is before my time. I can just kind of tell you a little bit of what I've learned from different people. At one point the State had made a decision to refrigerate the blood spots in order to basically -- and basically to -- what word am I looking for? To keep the spots more viable, I guess, in terms of potential research. So what happens is typically -- someone made a decision and I guess there's research and literature out there regarding this, that if you refrigerate the blood spots, basically the integrity of them are basically protected for a longer period of time, so that's all that means. At some point the State made a decision based on research that's out there in the research world that if you refrigerate these blood spots, then they'll last longer. The integrity, you know, and all those kinds of things are more viable or more from a liability perspective you can trust them, I guess, in terms of -- you can trust them more in terms of whatever research you're doing, so just the viability of the blood spot itself; it's supposed to last longer.**

Q Okay.

**A So they did that -- and I believe it's -- I can just tell you from -- I believe it's 2000 and -- I want to say for the**

**last -- we've had them about eight years. No, we had them from 2008 to current that are refrigerated in our Biobank.**

Q Okay. And when we talk about the ones before 2008, those would be just stored at normal ambient everyday room temperature, fair?

A **That's fair.**

Q Okay. However, would you agree that both pre-2008 ambient temperature spots, stores spots, and post-2008 refrigerated spots are both spots that have been made available for access for researchers or for the punches that are sought by researchers out in the public?

A **That's correct.**

Q All right. Let me ask this. I mean, I kind of skipped over and jumped ahead a little bit. What is your background in terms of scientific understanding? I mean, you're a doctor. I know you're Dr. Yancey. I've seen that on there.

A **Right.**

Q What is your background? What's your educational background and field of study.

A **So I'm not a scientist at all. I have a doctorate in organizational leadership, so basically my doctorate is all business-related. I do nothing with science at all in no capacity.**

Q So you're about like me. The extent of our knowledge is Band-Aids and Robitussin, you know?

**A There you go. There you go.**

Q All right. So good. We can speak on non-scientific terms going forward.

**A Yes.**

Q All right. The question you mentioned earlier that the State decided to, you know, for example, separate out refrigerated after 2008 and non-refrigerated ambient before that. What role does the State have in making such a decision like that as it applies to the Biobank?

**A What decision that they have?**

Q What I guess I'm trying to understand -- forgive me. I'm going to be a little long-winded here with this. What I'm trying to understand is the Biobank is a separate legal entity as a nonprofit.

**A Right.**

Q That's my representation to you. I think you even answered that earlier.

**A Right.**

Q But a lot of -- I see in the discovery that's been provided by the State and by Mr. Kennedy, who is your attorney, is that the State seems to be calling the shots. State officials over at the Michigan Department of Health and Human Services are calling the shots and making decisions about the use, storage, availability of spots, access to spots, and that the Biobank folks are following or otherwise

agreeing to that process.

**A Uh-huh (affirmative).**

Q Make me understand what the role is between -- again, let me start off -- let me strike that and start off by saying am I wrong, and then follow up by explain to me how can you -- how can you explain to me and vis-a-vis the judge what the nature of the relationship is between the state officials at the Department of Health and Human Services as it applies to all of these activities going on at the Biobank?

**A So the Biobank deposits -- or I guess there's two components from my perspective. One is that yes, you do have the State that is involved in all of the IRB approvals, all of the operation process, and so they're making those decisions at the state level. And then they've contracted us to basically be the bio depository just in terms of the storage, and so, I mean, to answer your question, yes, the State does make some calls, but primarily they don't make any calls regarding the depository bank within itself. That is a call that's made by the board, which as you can see is a collaboration. We have a person from the State, and then all of our other partners from the other universities that sit on this board, so it's fair to say that with some processes the State are making the call, but when it comes to the bio depository within itself, the storage facility, they're not really making the call for that. That would be**

**the board that's making the ultimate calls for that piece. So there are so many components before it gets to us, and that's when the State gets the lead on those components.**

Q And to be fair, when the board makes a decision, you as a role of the director, effectuate those decisions and whatever those decisions may be?

**A That would be correct, yes.**

Q So say, for example, going back to the example I was starting with with my son, and this is again just as a reference point for me. My son has got some blood samples, some dry blood spots in the Biobank right now. Let's say I wanted to get those -- I wanted to get those spots removed from the Biobank and I no longer wanted you to have access to them. Could I come to you, first of all, and say, "Please remove those spots"?

**A No, absolutely not.**

Q Why not?

**A Because I wouldn't even know how to identify your son's spots because there would be no -- there are no names that are associated with it, so I wouldn't even know, you know, where to go, where to pull it, what shelf it's on. I wouldn't have any of that information.**

Q Okay. Let me play another what-if.

**A. Okay.**

Q. Pretend I came -- for whatever reason I came to you with the

-- I call them -- I've seen them referenced in there, called ascension numbers? Is that fair?

**A. Yes.**

Q. Okay. I come to you with my son's ascension numbers and I say, "I would like" -- "These are my son's ascension numbers which identify the specific blood spot wherever it's stored in the facility. Go get those. I want those and I want to take them with me when I come to see you at your office at TechTown," right? Can I do that with you?

**A You cannot.**

Q Okay. Explain to me why not that in that sense.

**A Because our job is primarily -- we deal strictly with researchers. We don't have any contact with any of the general public in reference to pulling blood spots. It would have to go through the State, and then the State would communicate to me to pull a particular blood spot from the bank. We don't interact with the general public. We only interact with researches only when we've been given approval by the State of Michigan to interact with the researcher, but we definitely never, ever deal with the general public non-researchers.**

Q Okay. We're going to get into that in a little more detail in a couple minutes.

**A Okay.**

Q But let me ask this question: As you get talking about --

you know, let's focus on the example with my son, for example.

**A Okay.**

Q I want to be able to get his sample removed from the Biobank, okay?

**A Okay.**

Q. How can I go about doing that?

**A. You would have to contact the State of Michigan to request that they be pulled.**

Q So if the State of Michigan provided you with direction that said, "Hey, here is Phil Ellison's son's number. Go pull that one and we either want to destroy or otherwise give that sample back," you would act in accordance with that directive?

**A That would be correct.**

Q All right. And let's go the other way around. Let's pretend my second son is born, and the State hands off a sample to you and says, "Store this in the Biobank," you're working in agreement in concert with them to put it into the Biobank at the State's direction, fair?

**A I need you to repeat that question one more time.**

Q Sure; sure. So I was just talking about my first son.

**A Right.**

Q And we're talking about taking a sample out, so I have a second son.

**A** **Okay.**

Q And he's born today, right? Thank goodness I've only got one, but let's just say I have a second son, right?

**A** **Okay.**

Q His sample is taken. The State newborn screening program does the testing on it. They send that sample over to you and they say, "File this into the cooler."

**A** **Uh-huh (affirmative).**

Q Right?

**A** **Uh-huh (affirmative).**

Q I mean, you would be acting in accordance and in joint concert with them to put that material into the storage facility for long-term storage like all the other samples?

**A** **That's correct.**

Q Do you have any discretion or any option to say, "I'm not going to," -- as the director to say, "I'm not going to have certain samples come into my facility"?

**A** **No.**

Q Would there be any reason why you would deny storing samples?

**A** **No, not really. The only thing I can of that -- and this is not an issue today, but at some point there could be an issue of capacity, room capacity.**

Q Well, we're not at that point today, are we?

**A** **No.**

Q All right. Fair enough. Does the board of directors have any say on whether a sample is pulled for destruction or added, and the same example of son one and son two I've just been giving you, do they have any control over that?

**A Not at all.**

Q Let me ask this: Why not? Why don't you or the board of directors have any say in that, considering you guys are in charge of the nonprofit?

**A We are in charge of the -- our job again -- I'm just going to repeat this again.**

Q Fair enough.

**A It's to act as a storage facility on behalf of the State, so all our job basically is to store whatever spots the State is sending over to us. Our job is to store those and to keep them safe, obviously, too, but that's what we do, so the board doesn't have any decision in terms of, you know, what blood spots come, what blood spots get moved or pulled. They don't act in that capacity and, furthermore, the board is not responsible for the -- you know, the day-to-day operations are handled by me and my team of people, so they don't get involved at that level.**

Q All right. Let me ask this: The blood samples when they're stored at the Biobank, who owns them, if you know?

**A I'm assuming that the State of Michigan owns them.**

Q Okay. Now when you say -- and, again to be fair, I try to

be the fair attorney with these depositions.

**A Yeah; yeah.**

Q Do you know the State owns them or are you just simply guessing?

**A I'm guessing. I don't know. I should have answered that I don't know the information to that question.**

Q And that's fair. I only what you to answer what you can tell me here today, okay?

**A I don't know the answer to that question.**

Q Would you have any opinion, as the director of the Biobank, as to whether I own my son's blood spots that are in your bio?

**A My personal opinion or --**

Q Well, I mean, I'm asking -- I guess what I'm trying to understand is that there's blood, the blood spots come from the bodies -- I mean, live bodies, obviously, not dead bodies, but live bodies of children that ultimately make its way following the newborn screening to your facility at the Biobank. I guess I'm trying to understand do you, as the director of the Biobank, have a position as to who owns those blood spots?

**A Yeah. I believe that --**

MR. KENNEDY: I'm going to object just to the extent that it calls for my client to reach a legal conclusion, but other than that, Doctor, you can answer.

**A Okay. So this is just -- this would just be my opinion based on just my experience as a professor and knowing a lot about records and things of that sort. So the actual record -- the information, the content, belongs to the -- to the individual, and I would say that the physical, the tangible piece, probably would be owned by, in this case the State or healthcare provider if we're talking about medical records. So I think the content, you know, belongs to the patient or in this case to the child or the parents, and then the physical components, the actual cards and things like that belongs to the actual facility, i.e. the State Lab or the State. That's my opinion of how it should work.**

Q Okay. I'm going to --

**A And I say that because of the simple fact that I do know that if someone wants to have their card removed and just based on the requests that I get from the State of Michigan, that a card can be removed at any time. All the parent would have to do is request that it be removed and it's my understanding, and I just know this from my operations, that the State will then tell me to send the card back to them, and I'm assuming that card is destroyed at that time, and that's --**

Q Okay. Let me ask this, though, and I guess we can finish that thought here. I was trying to establish -- and forgive me. There's some questions I know the answer to these.

**A Yeah.**

Q It's just this is my opportunity to ask you to get them on the record.

**A Right.**

Q So bear with me.

**A Yeah.**

Q I was asking a little bit earlier about the concept of me coming to you to remove those cards, and you said you couldn't do that?

**A That's correct.**

Q All right. And you said -- I believe you answered, and if not, please correct me and tell me the answer, that the board of directors can't direct that a blood sample of my son can be pulled and given back to me or destroyed, correct?

**A That's correct.**

Q Okay. Who would?

**A The State.**

Q All right. Who at the State has that authority? Who do you take that direction from?

**A So we have a state coordinator that we deal with where most of our communications come from. Her name is Shelby, I believe, and I kind of went blank on her last name. But we have -- Atkinson, A-t-k-I-n-s-o-n. She's the liaison for the State of Michigan and that's pretty much who we have all**

**of our interaction with.**

Q Let me show you -- I'm going to pull up right here an email, a set of emails.

**A Okay.**

Q Let me see if I can make this work. Yep, here we go. Okay. I just want to use this as kind of a reference point, okay?

**A. Okay.**

Q. I know I made a big deal in the court case about the Trans-Hit Bio aspect thing and I know that never went to fruition, and I get all of that. But I want to show these emails here as a concept.

**A. Okay.**

Q. My understanding -- and I'm just -- to shortcut this, my understanding is that Trans-Hit Bio is a -- I call them a blood broker, but they're a sample broker that reached out to the Biobank to potentially make contact to buy or have access to blood spots.

**A. Okay.**

Q. Fair enough?

**A. I don't know really who Trans-Hit Bio -- I don't recall who this person is, but if you say --**

Q. Okay. Let's scroll down here because I think they emailed you originally.

**A. Okay. And they may have, yeah. Okay.**

Q. You're like me, you get 4,000 mails a day?

**A. Probably 10,000.**

Q. So here's an email, November 2nd, 2017, a woman named Sophie Dahan.

**A. Yeah, I remember this.**

Q. Okay. All right. As I understand it -- I don't want to get into the finer points of this, but I understand they reached out to you to see if they could potentially buy samples from the Biobank?

**A. That's correct.**

Q All right. So as I understand it, is that you forwarded that discussion to Dr. Shah and Dr. Lyon-Callo, and I'm going to show you up here -- oh, I'm sorry. I'm mistaken; let me correct that. You sent it to Carrie Langbo.

**A. Yeah.**

Q. Who is that?

**A. So Carrie Langbo is no longer with the State, from my understanding. The new person is the Shelby Atkinson person.**

Q. Shelby. That was going to be my question. Carrie -- Shelby is the new Carrie, correct?

**A. That's correct, yes.**

Q. All right. So you forward that email on to them, it looks like a couple of days later, about reviewing it and there's some emails back and forth to this aspect, but what I want to show here, there's an email back to Carrie where -- I'm

just going to again shortcut this. Dr. Lyon-Callo and Dr. Shah discussed this with Legal. They went back and forth with this and they ultimately decided that they did not want Trans-Hit Bio to be able to buy samples from the Biobank.

**A. Okay.**

Q. All right. Do you recall -- and then it looks like that they ultimately said, "Please thank Dr. Yancey for reaching out about this potential."

**A. Okay.**

Q. To me it appears that they're calling the shots about the use or access to those bio samples, those blood samples themselves. Is that fair?

**A. I think so, yes.**

Q. Okay. What role does Dr. Shah and Dr. Lyon-Callo play in regards to the Biobank?

**A. So Sarah I believe is the --**

Q. Let me be clear. So Sarah is Dr. Sarah Lyon-Callo, correct?

**A. That's correct.**

Q. Okay.

**A So Carrie at that time reported to Sarah. So I guess I'm -- so, yeah. We interact with them throughout the day, but they make the calls in terms of -- I don't -- my team, we don't get involved. When things come directly to us like requests for blood spots or, you know, what is the approval process, we send everything over back to the DHHS and**

**they're the individuals that make the decision in terms of who gets approved and who can basically use the blood spots for whatever research purposes. So I'm not involved in that piece, so to answer your question it is DHHS who is making those types of decisions or --**

Q Would Dr. -- I'm sorry. Go ahead. I didn't mean to interrupt you; go ahead.

**A -- or making the decisions in terms of who are and can use blood spots for whatever research purposes. So, again, going back, my job is strictly to act as a depository for the blood spots, so I'm not involved in these types of decisions at all, I'm not, and so in our guidance from these individuals, Sarah. Now, you know, again, Sarah is not here -- Carrie is not here. Shelby is our primary contact for the State of Michigan, so in terms of the approval processes and all those kinds of things, it's handled at the State level and not by the Biobank.**

Q Okay. Let me ask this: Is Dr. Lyon-Callo one of the decision-makers on behalf of the Department of Health and Human Services with the Biobank?

**A I'm not really -- I don't interact with her, so I don't know the answer to that, to be honest with you.**

Q Okay. And what about --

**A My (indiscernible) is copied on the email sometimes, but I don't even know if this person is still there because I**

**haven't seen her name in -- they have a lot of turnover, so there has been -- you know, there are a lot of people that I worked with when I first started in '17 that are not here anymore. It's constant, you know, turnover. They move on to different areas, so I haven't talked to Sarah in years, I don't think.**

Q Okay. Well, let me finish out, and as to Dr. Shah, is he one of the decision makers?

**A Yes, he is.**

Q So let me ask this question: If you got an email from Dr. Shah that said you're authorized -- the Biobank is authorized to disperse ten punches to a particular researcher, would that be in your mind authorization from the State?

**A. Yes and no. I've never got a request from him because he's not involved in the operations, but I know that Dr. Shah is in charge of the State Lab, so I would assume that it would be okay if I got a request from him, but that would be very unusual because he's not involved at that level.**

Q. Okay. What about if Dr. Lyon-Callo had sent you a similar directive by email that this particular researcher can have access to, say just as an example, ten samples?

**A. Yeah, because I believe at that time this was the director, and so, you know, if they send me a request to pull it, I would pull it.**

Q Okay. All right. Fair enough. Let's make a note here.
**A Uh-huh (affirmative).**
Q So I guess during all of this -- I guess to bottom line all of this, when you get a directive from the State to do something about the Biobank, you're acting in concert with whatever it is that they're telling you to do, fair?
**A That would be correct.**
Q Okay. Let's change gears a little bit. Okay. What role -- so let's talk about the Biobank just generally at a high level, okay?
**A Okay.**
Q As I understand, I think you confirmed earlier, it's a nonprofit corporation, correct?
**A Correct.**
Q All right. And we talked about your board of directors. What role does Wayne, MSU, You of M and VanAndel apply as to the operation of the Biobank?
**A So as I mentioned, for the most part it may have been a different arrangement prior to when I got there. It's supposed to be a partnership between all of the universities. I think Wayne, and that's probably because, you know, I guess Wayne is the person that's actually appointing the director of the operations. I think that Wayne State, by me being an employee of Wayne State and all of my predecessor, that we're probably more involved in the**

**overall operations than our other partners. It's each person sits on the board. You know, there is a university affiliation for each member on the board, and so again I think from a collaborative perspective you can get input from that way, but just in terms of operations I would say that Wayne State, primarily me at this particular given time, will be more involved. We -- I think when it first started it was more of a real partnership where they handled -- they donated the software to use for the scanning of the blood spots, and then the You of M would contribute some things financially, but that has changed, at least since I've been here. We're pretty much the primary coordinators in terms of the operations of the storage facility.**

Q Okay. Let me ask this: I'm just kind of covering different areas on this. We were talking about as I understand, each of those four entities appoints someone to serve as their representative on the board of directors, true?

**A That's true.**

Q Is any one of those particular individuals the current chairman or chairperson of the board?

**A Yes. That would be Ed.**

Q I'm sorry?

**A Ed.**

Q Oh, Ed?

**A Yes. He's the -- he acts as the president of the board.**

Q Do you know if that was done pursuant to any sort of vote or any sort of particular process?

**A I don't know that information.**

Q In the last year when -- I mean, let me ask it this way: Does the board meet on a regular basis?

**A We do. We meet twice a year.**

Q Okay. In the time that you've been on the board has there ever been a vote to nominate and accept Ed as the chairman or is it just gone without saying?

**A Gone without saying.**

Q All right. As part of -- let me see if I have that here. As part of -- as part of the discovery in this process, I have asked for a number of documents from the State Defendants that have been happily provided. I'm sharing with you what's been marked as Exhibit Number A for purposes of this deposition, and this is a document that was provided to me in response to that discovery. Take a moment and take a look at this.

(Deposition Exhibit A marked)

Q. Just let me know when you're ready.

**A. Okay.**

Q Okay. Taking a look at this, I've been asking you some oral questions about the nature of the relationship between the Biobank and the board of directors and the Department of Health and Human Services. Does this picture or graphic

accurately depict the relative relationships between those three entities that we've been discussing?

**A. Yes. Well, I can only speak for the Biobank. I can't speak on the other side because I'm not really sure about some of the -- I don't get involved with the advisory boards really. I do attend some of their meetings, but I don't understand all of the logistics regarding it. I can only tell you on the right side in terms of my reporting structure, how that works, but I do know that they do have a scientific advisory board. I just kind of know that information just from, you know, interacting with them and just in terms of when they tell me that someone has to get approval, so I know that there is a SAB board, but in terms of the community advisory or advisory board, I do know that they -- because I've participated in some of the advisory boards. I think they have a meeting once a year and I've been invited to attend that, but I can't go on record by saying that this is completely how their structure is because I don't get involved on their side.**

Q. Let me clarify my question. Let's take out -- looking at this graphic, if we take out the community advisory -- or community values advisory board and the scientific advisory board boxes, and we have the three that's left, and that was the three I was referencing, does the text and information as this is structured a proper diagram of how these three

entities, being DHHS, Biobank, and the board of directors fit with each other?

**A. Yes, those are correct.**

Q. And as they describe their services -- as they describe the bullet points in each box as to what each of them does, is that an accurate description of what each of them does?

**A. I can speak for some of the things in this black box for what they do. There's some I can't. I have no idea what they mean whey they say "honest broker." I mean, "public education." I'm not involved in that piece, so I can't --**

Q. Okay. Let me ask this question: In just the Biobank box are those statements correct?

**A Okay. Yes, it is. I'm not really sure about the -- they have MDHHS non-voting representative. I'm not sure what that means.**

Q. I'm sorry. I just want you to focus on just the Biobank box, not the --

**A. Okay.**

Q. Are those bullets there correct on what you guys do at the Biobank?

**A. Yes, that's correct. Let me clarify something, though. So it says assigned study specific ID codes to remain confidentiality, so I just need to clarify that because that's very important.**

Q. Okay. Please do.

**A. So what happens is that anytime that a study is approved by the State, that ascension -- the ascension number that we talked about, that eight-digit number, what happens is that when it says here, we also assign our own number too that's attached to that ascension number. So it's identifiable, and then we go through another process of doing another identifiable number by adding another two-digit or three-digit number on top of that number that comes in, so if a researcher ever needed to know, you know, what number was pulled for what, we're able to kind of tell them that. So if the number 12345678 comes from the State, we'll add a 01, 02, 03. It depends on how many spots they're given.**

Q Okay. So from that information, you could look at that number in your database and you could tell what spots have been pulled --

**A For that reason.**

Q -- according to what study then, correct?

**A Correct.**

Q Okay. If a researcher wanted to have access to the Biobank spots, say they needed a thousand of them just as a hypothetical.

**A Uh-huh (affirmative).**

Q Could they make that request directly to you and have that request fulfilled?

**A No.**

Q All right. What process would have to be -- as you understand it has to be fulfilled for having access to blood spots for research purposes?

**A We refer them back to DHHS for approval.**

Q What process, if you know, do they undertake? I don't need the scientific part of it. I'm talking -- I want to take this to kind of a 35,000 foot level. What process do they undertake to let you know -- well, strike that. Let me start that question over. See, I start with a great idea up here and it just doesn't come out through the mouth the right way. I guess what I want to know is what process do you understand occurs when someone wants to have access to blood spots and you send them over to DHHS? What happens before the point that it comes back to you and the State says, "Give them the 1,000 spots"?

**A So it's my understanding that it goes -- I mean, the researcher would have to elaborate on the reason, I guess, for the research, why they need the spots to study. It's my understanding that they go through a variety of different communities including the scientific advisory board, you know, if -- of course, if the research is even approved. And then it has to go through a variety of IRB committees for approval, so that's my understanding, but I don't know how the initial decision is made in terms of who they allow and for what purpose, and those kinds of things, so I'm not**

**involved and I don't understand that piece.**

Q Okay. But you would agree that you act in joint concert with the State, though. When the State says, "Give them these samples," you guys do it over at the Biobank?

**A Repeat that question.**

Q Fair enough. So what I'm wanting to understand is the State -- somebody at the State, be it Shelby or Carrie, says, "The State has approved this research study," you guys in agreement with them whether you -- you know, you basically hand over that material and agree to do so at their direction?

**A That's correct. So once a person is approved, we receive an email telling us that a researcher has been approved and eventually we will get a request to pull the blood spots, so they basically make the decision in terms of what blood spots are pulled from the depository.**

Q At that point right there, say you get a -- you get an email from -- like the email you were just describing that says, "Pull these 1,000 spots for," you know, to sell a punch, right, or provide a punch to a researcher. Do you take any steps to contact whose blood spots they are or their parents to get consent to give those samples out?

**A No.**

Q Okay. Why not?

**A Because we're not involved in that process. We're just a**

**storage facility.**

Q. All right. Do you know as part of -- at the time that a research project is proposed and being reviewed by the State and ultimately for approval, does the State attempt to contact the person whose blood spot that belongs to or their parents to get their consent as part of -- before giving out that particular spot?

**A. I don't know that information.**

Q. Have you ever heard of it happening?

**A. (Indiscernible) --**

Q. You cut out there for a second.

MR. KENNEDY: I'd just object to the extent it calls for hearsay.

Q Okay. Go ahead, Dr. Yancey. I should have explained when we do objections, unless he directs you not to answer, we fight it out with the judge later whether my question is any good or not. So you answer the question nonetheless, okay?

**A Okay.**

Q My question to you was have you ever heard of the State providing --

MR. ELLISON: Jeremy, I acknowledge your objection for restating the question.

Q. Have you ever heard of the State actually contacting the person whose blood spot it belongs to or their parents when approving a study?

**A. No.**

Q You as the director of the Biobank, do you require that consent be obtained from the person whose blood spot it belongs to or their parent prior to giving out what blood sample?

**A No.**

Q. Does the board of directors at Biobank require that?

**A. No.**

Q Has there ever been a discussion or decision about whether consent needed to be obtained before giving out samples? And again, this is in the context of when a study has been approved.

**A No.**

Q Do you believe as the director -- and again, I'm asking you as director, in your role of director of the Biobank -- that such consent is required?

**A Do I believe?**

Q Yeah, do you believe it's required?

**A It's my understanding that all of that is done way before it gets over to us at the Biobank, all the consent forms, just knowing a little bit about the process. You know, it's my understanding that the consent forms are all done, you know, way before it gets over to us in terms of the storage facility. So I've always assumed that there's been a consent filed -- a consent form on file.**

Q I'm going to ask you -- acknowledging this is a hypothetically question, I'm asking you this in your capacity as director of the Biobank. Let's assume for the sake of argument that that consent was not obtained from somebody's sample who is in the Biobank. Do you think you have an obligation to obtain consent before giving a blood spot for an approved study out to a researcher when that blood spot belongs to a person or their parent?

**A I think a consent form should always be, you know, the primary decision before any blood spot is given to anyone. But, again, I don't get involved in that process.**

Q Fair enough. I understand that. Let me ask this question: Do you as the director or anybody under you who is under your purview at the Biobank, do you guys check each blood spot to make sure of the -- let me try that again. That came out bad. I guess what I'm trying to -- what I'm trying to understand is do you guys -- when you get a statement or a directive from the State that says, "Give out these 1,000 blood spots to the researcher," do you guys go back and check to make sure that consent was obtained before giving out any of those samples?

**A No.**

Q Any reason why not?

**A For one, when we get the information, remember we're not getting any names. We're just getting a number, and so we**

**would have no idea who the blood spot belonged to to be able to get a consent form, and then if we were to get a consent form, then we would be exposed to someone's personal information and that's not how the Biobank is set up.**

Q Okay. Does the Biobank -- and, again. Forgive me. There's questions I know the answers to, but I've got to ask you as part of this.

**A Yes.**

Q Does the Biobank in any way ask or otherwise obtain its own consent form from each donor of the blood spot before putting it into the Biobank?

**A No.**

Q Same question except as to removing a blood spot and giving it to a researcher. Is any sort of consent obtained by the Biobank itself?

**A No.**

Q Does the Biobank store any of the consent forms -- let me back up. Let me preface this the right way. You just testified earlier that consent forms were obtained as part of the earlier part of the process.

**A I'm assuming that it was. I can't go on official record. I'm just giving you just, you know, general experience, just, you know, in seeing different emails and things of that sort and kind of understanding a little bit about when I first got in the role, I went on the internet and did**

**research about how this while piece worked and I've got a little bit of information. So I can't -- do you know what I mean? I just want to be clear that I don't -- I'm just telling you from I guess a private or personal, not in my -- not in my capacity as a director because I'm not involved in many of these components that you're asking about.**

Q Well, let me ask it this way. Let me ask you this way. Does the Biobank have access to or otherwise store any consent forms of any type related to the blood samples that are stored at the facility?

**A No.**

Q Do you know where -- if there are consent forms, where those consent forms would be stored at?

**A No, I don't know where they would be stored at.**

Q Let me ask kind of a weird question. Let's just assume for the sake of argument that the judge in this case finds that consent was not properly obtained, and these samples are being held contrary to consent. Do you have the -- if the judge was to order you to return these samples back to their owners, would you have the authority to direct your employees to fulfill that task?

**A No.**

Q Who would?

**A The State.**

Q And when you say the State --

**A The reason why, we wouldn't know -- if the judge -- if there was an order that came through, I wouldn't be able to return them because I wouldn't even know who they belonged to because we're not able to identify the individual. Because we operate as a 501(c) company, I'm assuming that if there's a court order and they said, "You've got to give these blood spots up," I would refer them back to the State.**

Q Let me ask you this: If the judge -- again, I'm acknowledging this as a hypothetical, okay? If the judge says, "These samples have to be destroyed." Would you have the ability to destroy those samples as the director of the Biobank?

**A No.**

Q Who would be the person that would have to make the decision to destroy those -- or would have to be the one to give the command to destroy those samples?

**A I'm not sure who that person would be, particularly at the state level, but I would assume that it would have to be someone at the State level because that's who we interact with.**

Q Okay. As I understand, there is a postextraction request system that's been put into place that allows parents to ask for samples to be destroyed after they've gotten into the Biobank, true?

**A I don't know about that system.**

Q Okay. Have you ever been, as the director, know about or seen or otherwise been directed by anybody at the State to destroy samples at the request of a parent?

**A We do not destroy any samples. We've received requests to pull samples.**

Q Okay. So let me just give you a -- well, I'll give you a straight-up one. I made such a request when I found out my son's blood samples were in your Biobank, okay?

**A Okay.**

Q I filled out the form. I sent it in. A few weeks -- a few months later after I sued them -- that's another issue; don't worry about that -- I get a letter back that says, "Your son's samples have been destroyed."

**A Okay.**

Q To your knowledge, how would those samples have gotten out of the Biobank and been destroyed, if you know?

**A So what happens is when those -- I do kind of recall that form now. So any time that form is completed, what happens is we get an email -- I get an email basically from the State and the State basically tells me to pull ascension number blah, blah, blah, and then I go into the storage area and we pull that blood spot. We're getting daily blood spots every single day from the State of Michigan, you know, all of the current ones that are being done and there are still older ones that we're still trying to get stored, so**

**there's a bag that we get every day with the current blood spots, and what we do is we put that particular blood spot, based on the number that they emailed us about, and we put it in a storage bag and, you know, there is a piece of paper we complete that basically -- it's like a little carbon receipt just to let them know that -- we keep a copy on file so that we know for a fact that they requested that and we put that in the catalog spot, and we send it on its way to the State.**

Q Okay. So this kind of brings me back to where we started on this discussion of the idea if I wanted my son's blood sample destroyed, I can't come to you. I can't come to your board of directors. I've got to go through the State officials at DHHS?

**A That's correct.**

Q All right. Okay. Let's switch -- I'm going to take this off for a second, and I'm going to open up another one. Oh, here it is right here.

(Deposition Exhibit K marked)

Q. All right. I'm giving you what I've marked as Exhibit K for purpose of this deposition. Again, I'll represent to you this is a document that the State Defendants provided me as part of the discovery process.

**A. Okay.**

Q. As I understand looking at this form -- I'll give you a

chance to look at it -- this is the price list for getting access to samples and/or portions of samples, which I've come to learn is called punches or a portion of that blood sample.

**A. Correct.**

Q. Take a look at that and see if you can confirm that this is the case.

**A. So, yeah. What you're showing me is a listing of what we charge for the processing of blood spots. Not the processing, but the administrative costs that are involved with processing.**

Q. Okay. So if, for example, I was a Michigan academic, meaning I'm taking that to mean a Michigan university researcher, and I wanted a whole random sample punch, a whole spot, for example --

**A. Okay. Let me back up a little bit. I'm taking a look at this, so this particular -- this is not -- this is something -- so there are costs that the State has, and then there are charges that we have on our end. This is not one of our documents that we have for the Biobank, so this doesn't look like -- yeah, this is not -- I don't know what this is.**

Q. Okay. Let me ask this question --

**A. Yeah, I do have -- we do charge. I do have a -- we do have our own price list, but these are not our rates at all. This is something that the State does. They charge, and**

**then we charge also.**

Q. All right. That's something new. I haven't -- you've just educated me on something I did not put together before, and so I want to explore that a little bit, so my questions may be a little weird in that respect. Looking at this spreadsheet right here, are these the prices the Biobank charges researchers?

**A. These are -- this list is not a current list. I don't know how old this is, but this is not -- it's very similar to this amount, but these amounts don't look familiar. We have like a three-layer tier system for our blood spots.**

Q. If you have a request to get access to punches or whole spots for distribution to a researcher or to a -- in my mind I want to use the word "customer," but someone who's trying to get access to the spots themselves for whatever purpose, do you guys have a price list that I could get access to?

**A. Yes. It's on our -- if you go to our -- it's on -- I believe it's on our website, but we have our own price structure that we can get you a copy of.**

Q. Okay. What I'm going to ask you to do is would you get a copy of that to your attorney?

**A. Okay.**

Q. So I'm going to make a request for that because this is something I've never -- I've always -- well, I guess maybe I've wrongly assumed that this was the price for the whole

package on the thing.

**A. No, and you know what? I don't know if this is an older -- it doesn't have like the Biobank on here. I don't -- this -- this just doesn't look familiar to me. I'm just going to be honest with you. I don't know. I do know that the State also does charging on their end and we charge on our end, but this doesn't look like -- I know for a fact this is not my current pricing system. It could be an older document that you have and they've changed the way -- the Biobank had changed the way in terms of the payment structure. It looks familiar just in terms of the prices are a little bit close and some areas are not. We only have a three-tier system, so this has -- one, two, three, four, five; out of state academic, out of state government. I've never seen this, so I don't know what it is.**

Q Okay. All right. So just, if you could, get that over to Mr. Kennedy, and I'll make that request, you know, in due course.

**A Okay.**

Q Let me ask this question, and I'm kind of just flying by the seat of my pants right now. If you guys -- the State charges whatever it charges. Biobank charges whatever it charges. Do you guys send your bill to the State so they added onto this, do you know? Or do you bill directly to the researcher?

**A No, we bill directly to the researchers.**

Q All right. And what happens to that money that you guys collect?

**A It comes back into the Biobank.**

Q Okay. So it just gets put into the general fund of the Biobank?

**A Yes.**

Q Do you guys know if you get any of this money -- again, let me just -- we'll just assume for the sake of argument right now that what you're looking at right now as Exhibit K is the price list that the DHHS charges the researchers.

**A. Okay.**

Q. Do you know if you get any of that money or a percentage of that money at all?

**A. We do not.**

Q. That's going to transition me to my next bar here. How does the Biobank operate in terms of funding?

**A. Okay.**

Q. How does -- what kind of -- I mean, looking at this, looking at the number, I'm going to represent to you from the data the State sent me, 63,009 samples have been provided so far, at least as to what's been disclosed to me. That works out to about -- assuming -- even assuming it's $9 a piece, I mean we're talking a half a million dollars. Maybe it's a little bit more. How does the Biobank operate in terms of

funding?

**A. So we operate a variety of ways. We have a variety of funding that comes through to pay for the operational expenses with the Biobank. One is that we get a grant from the State of Michigan every year and that grant is approximately 140,000, I believe, per year. It's actually -- it's actually -- I believe it's 154. 14,000 of that money goes back to the University in what we call indirect costs, and that's just the money, the F&A that comes back to the University, so our actual physical amount is $140,000 from that grant. We use that, and then we also use the money that we collect for the spots, for the processing, the administrative costs that are associated with the processing of these blood spots for the researchers. Our average charge is currently -- I believe it's $10 per punch now, and so the money we collect from that goes into the operational cost. And then also there are some other funding sources, for example, we have students that are employed by Wayne State University that is paid by Wayne State University, but they actually help process the blood spots for us, so that's not --**

Q Is that like work-study kids?

**A Correct. Work-study, and then we also have what's called temporary technicians, so these are people that are basically -- they don't meet the eligibly of a full-time**

**student or part-time student, and we can hire them as a temporary worker, and then we just pay them a salary.**

Q Okay. All right.

**A And they get paid by -- everybody gets paid by Wayne State University, and then we also have an operational manager full-time that works for the Biobank and he's also paid. Then we have a variety of other different operational costs like rents. We have to pay for the freezer bank itself. We have a big high payment that we pay, so basically all of that money goes to the operational expenses. The grant doesn't cover nowhere near -- probably the grant covers approximately I would say 40 to 50 percent of our overall operational expenses.**

Q Okay. Do you get any money from any private sources?

**A No.**

Q Do you get any money from -- setting aside, obviously, the work study, the salary part of this with the kids and the temporaries, does Wayne State, U of M, MSU, and VanAndel, do they supply any money?

**A No, not currently. We would like for them to, but --**

Q. Yeah, right.

**A. -- they don't. I believe at one point prior to me it used to be more and I was explaining that earlier. It was more of they give financial contributions, but I think over the years that's changed and Wayne State would be the primary**

**person that would basically donate on behalf of the --**

Q Okay. The pricing that you guys charge that we're talking about that goes back to your general fund as part of your funding, prices you charge for the punches, is that something that's established by the State or your board of directors?

**A It's established by the board of directors.**

Q Does that have to be approved by the State at all? Do you know?

**A No, it does not.**

Q Understanding you're not an attorney and have probably a better life, do you happen to know if there's any legal authority that authorizes the Biobank to charge fees for providing those samples?

**A I have no information of that, no.**

Q And once you guys determine whatever the fee is, you just -- I mean, is it like an invoice you send to the researcher?

**A Yes, we send them an invoice. We have a billing system.**

Q Let me do this: I'm going to see if we can just -- just as an example for this -- yeah, right here. I'm going to present to you what is -- your lawyer -- your lawyer provided me a whole bunch of documents.

**A. Okay.**

**(Deposition Exhibit F marked)**

Q. This is Exhibit F for purposes of this deposition. Here it

is. Okay. This would be -- I'm presenting Exhibit F. This would be an example of an invoice you would send in this, "Future Diagnostic Solutions"?

**A. Correct, yep.**

Q. All right.

**A. Can you go down a little bit? I want to see the title of the --**

Q. This?

**A. Yeah, yep. Okay. Thank you. I wanted to make sure it's our invoice. That's a copy of our invoice.**

Q. Okay. All right. And the second page of this is -- with counsel's okay I will produce these. I'd like to be able to redact the account number.

**A. Yeah, I was going to say we really need to redact that.**

MR. ELLISON: Jeremy and Aaron, would you have any objection to me redacting that when I submit those to the court reporter?

MR. KENNEDY: No.

MR. LEVIN: No.

MR. ELLISON: Okay. All right. I think the same thing here. They've got an account number here on these checks as well.

Q This, for example -- I mean, this would be a check I've seen made out to the Biobank which matches the number right here?

**A Yep.**

Q And so you guys would get a payment?
**A That is correct.**
Q Okay. But just -- I mean, I guess to kind of finish this thought out, though, you would not have sent them these samples unless the State had approved for you guys to send the sample?
**A That would be correct.**
Q Okay. We're almost done. A couple of details I just want to get ahold of. As I understand from the various pieces of literature I've seen, there are samples that are currently within the Biobank that go back to -- I've seen a 1984 and 1987. Do you know one way or the other how far back the samples go that are being stored?
**A. Okay. So this is always a hard question for me and I started to write it down for you. So we have '96 and current -- '96 to current. When I say current, give and take that it takes --**
Q. Well, you're getting samples every day, you said, so --
**A. Well, yeah, but then they're doing the testing. It's at the lab, and so it takes about -- it's a two-week lag time, I guess is what I'm trying to tell you, but we should have everything from '96 to current.**
Q. Okay. Is there -- so on the -- on some of the literature it says -- even some of your own literature is saying that it goes back to like the -- I've seen one that says July of

1984, another one that says 1987.

**A. Yeah.**

Q. Do you have any information about if that's true, how far that goes back?

**A. I don't know how far they go back, but I do know that -- and I should tell you this, that every day we get current blood spots and then sometimes -- the plan is to eventually have us to store all of the blood spots from when the program first started, and I believe it was '84, maybe '85, I thought. I don't know. But in any case, there's a backlog to get those spots over to us, so sometimes we get current and we may get something, you know, from -- since we're in 2009, they would go to 2008. So we would get some -- you know, some of the older spots for us to store for 2008. The plan is to eventually have them all housed and stored with us, but the State hasn't been able to get those older spots to us because there is things they have to do on their end. So eventually, the plan is for us to have all of the spots from when the program first started when the State started testing. I don't know how feasible that would be, as the director of the Biobank, because we wouldn't have -- I mean, I mentioned earlier there will be room capacity issues and we're going to run into that problem in a couple years, and so that will need to be a conversation that we have with the board. But we do get -- we're current getting older stuff**

**and we get current stuff at the same time.**

Q Let me ask you this: Say I wanted -- I'm a researcher and I want samples from 1988, for example. Where would those be stored? Where would I get those?

**A You would get them from the State.**

Q. Do you know where the actual physical samples from 1988 are stored?

**A. I think it's in your own State Lab. Somewhere in the State Lab is what I understand.**

Q. I mean, you don't know for sure one way or the other?

**A. No, I don't.**

Q. Okay.

**A. I just know that it's at the State.**

Q. Let me ask this question: I've learned that there's a storage facility that the State has that's storing samples in Lansing off the -- not at the lab site, but at an offsite storage facility. Does that help at all in refreshing your recollection at all?

**A. No, it doesn't. I don't get --**

Q Fair enough. At your -- for the samples that you do have, who has actual physical access to those samples?

**A Just me and the operations manager that I have there.**

Q. So that was Chris?

**A. That's Christopher Kraus.**

Q. Is he still there?

**A. Yes, he is.**

Q. Okay. Another question that I'm hoping you can answer is how many samples do you think you have at the Biobank?

**A. I could not tell you that.**

Q. I mean, are we talking hundreds? Are we talking --

**A. I could probably tell you that, but it would take me some time to tell you that. Let me clarify that. We have thousands and thousands. I mean, the room is -- we've got -- I mean, we have hundreds of thousands of them. I could tell you that; it would just take me a little while.**

Q. I've heard -- I've heard that the State's got 4 million and I've heard they've got 7 million. I've heard -- I mean, the numbers -- I was just curios if you knew offhand on that.

**A. No.**

Q. Okay. Are you familiar at all -- you somewhat hinted at it earlier, but are you familiar at all when the State has made the assertion that they act as the honest broker?

**A Uh-huh (affirmative).**

Q Do you understand what that concept means at all?

**A No, I mentioned that earlier. That's the first time I've ever seen that.**

Q Do you have the ability, if I was to come down there and say, you know, "Dr. Yancey, I'd like you to" -- "I got approval from the State because I'm here on behalf of the Court. I'd like you to pull a sample of my sister's child,"

for example, and I know you somewhat answered but I want to make sure I've got it clear for the record. I come down there. You haven't talked to the State. I haven't talked to the State. I just have an approval from the judge to say, "Go get Phil's sister's son's sample," right?

**A. Uh-huh (affirmative).**

Q. Do you have the capability to be able to locate that sample if I was to do that say tomorrow?

**A. With a name?**

Q. With just a name, yes.

**A. No, no. There are no names at all on anything, any blood spot out of all of the hundreds of thousands that we have. No name.**

Q Okay. But to be clear, you couldn't go to a computer also and say -- type in this guy's name or the kid's name or birth date or some other thing and look up and say -- unless you actually have that number from the State to correlate it; fair enough?

**A That is fair.**

Q Okay. So sorry because I actually split my question there. Let me make sure I get it clear the right way.

**A Okay.**

Q So you would not have the ability, for example, to type in a child's name, social security number, date of birth and be able to find that sample from your computer or any sort of

index onsite at the Biobank?

**A That is correct.**

Q Okay. So by extension, my next question, which I kind of veered into was that the only way you could pull a particular person's sample would be if the State provided you with the ascension number that is associated with that particular sample?

**A That is correct.**

Q At the facility do you maintain any other data -- well, let me ask it this way: Any other data that you maintain relative to the samples? And let me give you some examples of what I mean. Child's name, blood type, date of birth, their weight when they were born, the time that they were born, any physical or physiological data that would allow you to associate with a particular sample?

**A No.**

Q Let's pretend -- I'm just going to -- let's do a pretend here. This is a hypothetically. I want to pull -- I'm a researcher. I want to pull 100 samples of blood samples from children born after the Flint water crisis, and I want to be able to see what -- I'm researching something with blood, right? Do you have any capability to be able to say, "I can pull these samples based on the zip code," for example?

**A No.**

Q All right. Could I do that with information -- could I -- well, let me ask you this: If I wanted those samples, is there some way that you know of that the State could provide me with a list of ascension numbers to be able to pull those samples?

**A Yeah, I'm certain that -- yeah; yes.**

Q Okay. So the State has the data, you have the blood?

**A That's correct.**

Q All right. Do you know what information is available from the State in terms of data associated with particular -- with individual blood spots?

**A No, I do not.**

Q Is there any sort of documentation that you guys -- you know, what if I was a researcher contacting you saying, you know, "Dr. Yancey, I'd like these" -- "I'd like the samples with these particular characteristics," how would I go about getting that?

**A. So they would be referred back to Shelby at the State of Michigan and I'm sure that they have a way that, you know, they can identify that information at the State level, but I don't have that information.**

Q Fair enough. Fair enough. Okay. Acknowledging our joke at the beginning about Band-Aids and Robitussin, humor me.

**A Right.**

Q Do you have any knowledge or expertise as to what sort of

information can be extracted out of blood samples?

**A No.**

Q I have these -- my questions into blocks. You've answered a lot of them here. Forgive me if I asked you this: You said you're not dealing with any aspect of the consent process for the ongoing storage, use, or research uses for the blood samples, correct?

**A Correct.**

Q Let me -- I'm going to share a screen with you right here.

**A Okay.**

Q We're on the downward slope. It took a little longer than I thought, but we're almost done here.

(Deposition Exhibit E marked)

Q. I'm presenting you what's been marked by the deposition as Exhibit Number E. These have been provided by the State and I'm just going to scroll through them real quick, just kind of in a slow scroll, but if you want to look at anything in particular please let me know. These as I understand are various consent forms that the State claims provides consent.

**A. Okay.**

Q. It's my representation, not necessarily the State's representation.

**A. Gotcha.**

Q. Looking at these, have you ever seen these forms before?

**A. I've probably seen it once in our operations book, just a general form. You know, I think I've seen this when I first started, just a copy of the form, but I don't get any of these forms.**

Q. I'm going to again represent to you this is my representation, not necessarily the State's or anybody else's, but my representation is that if these are in fact the consent forms, there's no reference to the Biobank anywhere in these documents. My question -- I want to make sure. I want to be 100 percent clear. There are no other consent forms related to the Biobank that you're aware of, fair?

**A. So the Bio Trust is the Biobank.**

Q. Okay. You're jumping to my next section, believe it or not, but we can jump to that right now because I'm trying -- that's one of the questions I want to -- I haven't been able to get a clear understanding on, but bear with me for just one second here. Let's just separate out the Bio Trust for Health as something for a second, just set that aside.

**A. Okay.**

Q. Looking at these forms, these are not forms that you -- you or the Biobank have created, correct?

**A. Right.**

Q. All right. And again, recognizing whatever the Bio Trust is. We'll talk about that in a second. There's no other

consent forms at all that you have on file, obtained, or executed or got in any way related to the blood samples, true?

**A. Correct.**

Q All right. Did you have anything -- and I say you meaning the Biobank, the Biobank have anything to do, to your knowledge, with the drafting of these consent forms?

**A Not during my time.**

Q Okay. Fair enough. And again, I appreciate it. Just what you know, okay?

**A Right.**

Q I'm going to make one more representation to you. For example, let's take a look at -- not the best copy in the world, but this is a copy -- this is, for example, Ms. LaPorte's son, and this one is -- this is -- just for reference, this is a consent form for the child we've identified. By federal law, we've got to identify them by initials for federal court purposes, but it's Child EMO. Looking right here, Ms. LaPorte indicated "No, my baby's blood spots may not be used for health research." But it goes on to say right below that the blood spots will be stored forever, but not used for research. Is that -- do you have any information or explanation as to why when someone does not want -- when a parent does not want their child's blood spot being used, that the blood spot will

nevertheless be stored forever?

**A. No.**

Q Do you have any information as to whether or not a blood spot will or will not be included as part of the Biobank storage program if they click or select no, they don't want to be part of any health research?

**A No.**

Q Does the Biobank have any sort of process or procedure in place to identify -- that they know of to identify those samples that are in the Biobank but do not want to be part of the research or potential research projects?

**A No.**

Q Again, would you agree that that would be information that probably would have to be obtained from the State?

**A Correct.**

Q You answered that. Do you know of any details or standards by which parents are told about the Biobank program during the time that consent is being obtained?

**A No.**

Q Have you been asked or otherwise -- strike that. I take attorney/client privilege very carefully. Have you ever ascertained by your own actions or directed someone at your direction to determine whether or not the nine children who are part of this case, that their samples are within the Biobank facility?

**A Have I? Repeat that. I'm sorry.**

Q Fair enough. I just want to you know if you or Chris -- because you had mentioned earlier that only you and Chris have access to the samples themselves, correct?

**A Right.**

Q Have you ever been asked or directed to go and check to see if these nine children's samples are in the warehouse, the coolers?

**A No; no.**

Q Do you know a Harry Hawkins over at DHHS?

**A No.**

Q Do you know -- I'm just -- Harry Hawkins passed away in the course of this case. He worked at DHHS. Do you happen to know what position he held or -- what I'm trying to find out, do you know who his replacement is?

**A. No, I do not.**

**(Deposition Exhibit B marked)**

Q All right. The last -- I'm down to the last piece here. I'm going to show you -- let me go through the exhibits here. Can you see that -- without me redoing that, can you see the like bluish-purple graphic?

**A. Uh-huh (affirmative).**

Q. Okay. Good, so I don't have to redo that. All right. Taking a look at that, and we can zoom in if we need to a little bit, take a moment to take a look at that.

**A. Okay.**

Q. Okay. Does this accurately depict your understanding of what happens to leftover blood spots after the newborn screening process is complete?

**A. I can't really answer that. I mean, I can answer some parts of this document, but some I could not.**

Q. Okay. One of the things I -- again, this is my representation.

**A. Okay.**

Q. One of the things I've learned as part of this is that of the blood spots that are the leftovers, some of them are stored by the State and the balance of those are sent over to you at the Biobank. Do you know that to be true?

**A. Yes. I do know that they keep -- they do reserve some spots, and then they send the rest over to us for storage. I do know that piece.**

Q. Okay. So there's actually -- in addition to your storage facility, there is a second one with similar blood spots, some within the State DHHS system?

**A. I do understand that to be correct, yes.**

Q. Do you know why -- do you have any knowledge or understanding as to why the State has these two separate processes, meaning one being you with the Biobank and one being them with these other samples?

**A I don't know that answer, but I do know that sometimes they**

**have to go back and retest things, I guess, and they want it to be readily available. I really don't know the answer.**

Q Do you happen too know where physically those other blood spots, those -- the ones the State retains but doesn't send to you, where they store those at?

**A. No, I do not.**

Q. You're not in charge or responsible for the storage of those in any way?

**A. No, I'm not.**

Q. Do you know what the State uses those other blood spots for? I mean, you mentioned -- you said you had suspected about other testing, but do you specifically know why they -- what they use those for?

**A. No. I've just heard that they use it for to retest at times, but I don't know the answer to that, I guess.**

Q Let's see here. So let me -- can you see my mouse?

**A Uh-huh (affirmative).**

Q All right. Good. Right here, this spot right here, this one blood spot is stored by the State Lab for only your personal use if needed. That's not the Biobank, correct?

**A That's correct.**

Q All right. Not to put words in your mouth, but I'm looking at here, your likely -- your option A and option B, correct?

**A. The blood spots go into a safe storage (indiscernible). Yeah, I'm A, and then the blood spots go into safe storage**

**and will not be used for research to treat -- yep, and I could be B, but the State could possibly be B too.**

Q. Okay. All right. Can you explain your knowledge as to what is the Michigan Bio Trust for Health, as opposed to or different from or the same as the Michigan Neonatal Biobank?

**A. So I'm going to be real honest with you. I'm not that savvy in that area.**

Q. I'm glad you're honest. I appreciate that.

**A. This was before my time. I've tried to understand it and read on it a little bit. This is my understanding: So the Bio Trust was set up, I want to say -- I can't remember the year. It was set up as a program to manage the operations of the storage -- of the blood spot storage. Why it was set up that way, how they became a 501(c), blah, blah, I have no idea. I just -- I was just told, "This is your new area and you're going to be managing" under my other 50 million areas that I manage. But that's how I got involved in this. I didn't want it. It just came to me because the boss said, "You're going to have it," so I haven't had -- you know, I don't know the history, to be honest with you, you know, about the whole -- the Biobank and why they chose to set it up the way they did. I don't really have that information. I know that the Bio Trust, I can say this, that it's a variety of stakeholders, so you have the partners with Wayne State and You of M, VanAndel, et cetera, the State, you**

**know, so there are a variety of stakeholders that are involved in, you know, the management of that, and that could have been the reason why it was set up as a trust, but I don't have that history.**

Q. Okay. Fair enough. Lastly -- or actually, I've got -- the last exhibit I want to show -- well, let me make sure. Let me look here. Just a couple of small follow-ups. Looking at --

(Deposition Exhibit G marked)

Q. I'm presenting you what's been marked as Exhibit Number G for purposes of the deposition. This has been provided by the State as the -- what I call the old brochure, and that's my name I give it, the one before the current one that's out called "After Newborn Screening." Do you have any -- did you have any involvement with the drafting of this document?

**A. No.**

Q. All right. Have you -- do you use this document or otherwise know of this document for purposes of the Biobank's operation?

**A. I don't -- this looks like -- I think I may have seen this at one point in the office. I'm not sure. It looks a little -- it doesn't look like a current one. I don't know how old this is, but I've seen -- I think I've seen this document before.**

Q. Okay. Does this --

**A. It looks familiar.**

Q. Okay. Let me ask this question: Does this document to your knowledge control or otherwise are a part of the way you operate your Biobank?

**A. I'm not understanding that question.**

Q. I guess let me say it this way: This is something the State created, it's not something the Biobank uses for its operation; would you agree with that?

**A. Correct.**

**(Deposition Exhibit H marked)**

Q. I'm going to present to you now what's Exhibit H.

**A. Okay.**

Q. Again, this is what I call the new brochure.

**A. Okay.**

Q. There's two sides to it here. Did you have any involvement with the drafting and the putting together of this particular brochure?

**A. No, I do not.**

Q. Okay. Do you know if your predecessor did?

**A. I don't know that information.**

Q. And again, this is not something you guys created, used, or maintain as part of the Biobank operations, fair?

**A. Okay. So when you say use, I will have to tell you that I've seen some of these at the facility.**

Q. Okay.

**A. So sometimes what happens is that -- and I don't know if this is the right one, but we obviously do promote the Biobank at Wayne State University for our researchers, and so I've attended different -- any time that we hire faculty, part of my job is to promote the Biobank for research purposes to the researchers, so I've used some of the pamphlets that have already been created. I use those when we do what we call new faculty orientation, so I may share that information along with some other promotional type stuff.**

Q. Okay.

**A. So the Biobank is promoted for research purposes so that -- you know, so that new faculty know that we do have a way of -- you know, of using blood spots for research.**

Q. Okay. I want to get that zoomed in here. I want to draw your attention -- if you can, make sure you can see. On the bottom left-hand corner on your screen where I'm circling the Certificate of Confidentiality.

**A. Okay.**

Q. Do you see that there?

**A. Yep.**

Q. Okay. Does that -- does the Certificate of Confidentiality mean anything to you regarding the operation of the Biobank?

**A. No.**

Q. All right. That's not something that you know about that

was either sought or petitioned for under your directorship?

**A. No.**

Q. All right. Okay. Two more here. I want to zoom out here.

(Deposition Exhibit O marked)

Q. This is a document that I will represent that used to be on your old website. I'm not sure if it made the transition in the time from the update. Do you recognize this?

**A. I do.**

Q. All right. Is this one of your brochures?

**A. It's one of my brochures, correct.**

Q. All right. Was this something you created or had created?

**A. I made modifications to it when I came onboard because some of the information may have changed.**

Q. Okay. Can you tell --

**A. My marketing department -- I have a marketing department that does all of our brochures and things.**

Q. Okay. Fair enough. And again, I don't know if I said it but this is Exhibit O for purposes of this deposition. Looking at -- if you can look toward the top right-hand side, I'm looking at those carts, that picture right there.

**A. Yep.**

Q. Is that the carts of how the blood samples are stored?

**A. That is correct.**

Q. And again, it's up to you if you want to take a chance to read this here, but based on that you acknowledged that this

is a Biobank brochure, the information contained in it is accurate at least as of the time that they made the brochure; would you agree?

**A. That is correct.**

Q. All right. Fair enough. Lastly here, before I go to the Complaint, this one right here.

(Deposition Exhibit L marked)

Q. To your knowledge, these are -- I'm presenting to you what's been marked as Exhibit L. These are various documents I've got as part of another lawsuit I have going against the State, myself and my wife.

**A. You scared me there for a minute. I see this charge of open murder and I thought -- the first thing I thought, oh my God, did I -- have I been charged for something that I don't know about? My heart just literally dropped there.**

Q. Well, I can tell you I'm not charging you with nothing on that whatsoever, so anyway, these are documents that were in response to the other case in which I asked about whether law enforcement had access to the samples at the Biobank.

**A. Okay.**

Q. These are some of the documents -- and I'm representing to you that were provided in response to that discovery in the other case.

**A. Okay.**

Q. Do you recognize any of these documents as something that

you had to deal with?

**A. Yeah. I remember either myself or my manager, I remember getting this or something like this when we first started. He may have gotten served with something.**

Q. Okay.

**A. I do remember this. It was probably at the beginning when I first started, because -- what's this, 2017? '18? Yeah.**

Q. They blocked the date. I don't know. That's --

**A. Yeah, I remember being served or he got served for this.**

Q. Okay. Do you recall whether or not the subpoena -- just whatever the document was, and I would represent it's a subpoena of some sort, that those -- that the samples were provided in response to those -- that legal demand?

**A. I wouldn't know that information because this particular -- this particular document was referred over to the State.**

Q. Okay. Do you remember at all whether the Biobank pulled any samples in response to a subpoena?

**A. I wouldn't be able to give you that information because I wouldn't even know who it was, so we get requests all the time from them to pull something, so I wouldn't be able to know if that number was associated with this person.**

Q. Okay. So I don't want to put words in your mouth, but just you would have got -- if there would have been a subpoena to the State, for example, like, for example, right here, the one I have in front of you on the screen. It's page 2 of

Exhibit L and someone is being charged with open murder and it was subpoena directed to the Department of Community Mental Health, State Public Health Lab Lansing, care of Harry Hawkins. If they had gotten that and they needed to provide that to the court, this would have just been a request to your office to pull like any other request would have been?

**A. Yes.**

Q All right. And you don't know any firsthand knowledge of actually receiving a subpoena yourself?

**A No. But we've -- like I said, I'm not sure. We've gotten -- I remember one subpoena since I've been there and again, I don't know if it was for this person, but I do remember being served. It may have been -- it may have been actually for this case, so I don't -- I don't know.**

Q. Okay. But you can't --

**A. In any case, if I had gotten a document like this, it would have immediately went to the State of Michigan.**

Q. Okay. Fair enough. And you don't know sitting here right now whether or not these subpoenas or legal demands were otherwise fulfilled, correct?

**A. No.**

Q. Okay. Let me just check. I've got one more -- I'm done with the exhibits. Let me just look right here. Forgive me. I may have asked this. I'm going through the

Complaint. I just have a couple of notes on my Complaint that I filed on this. I just want to ask a couple questions on that and you may have answered it, so forgive me if I'm asking you again. If I -- no, strike that. You've answered -- no, you've answered that. I was just -- you've answered that, so. Does the Biobank have any policies about providing blood samples or blood spots to public or university researchers versus for-profit companies?

**A. No.**

Q. I've noticed -- and I don't have it on the screen right now, but the State provided me a list of research projects and for example, I see companies like Luminex, Genomics (ph) USA, Astoria Pacific, Advanced Liquid Logic, Asuragen -- A-s-u-r-a-g-e-n, like for example, you guys provided 10,000 samples to them, for example.

**A. Uh-huh (affirmative).**

Q. These are all for-profit companies I've discovered on that. There's no -- to your knowledge, there's no prohibition or concern about providing samples to a for-profit company?

**A. I don't get involved in that information.**

Q. All right. Fair enough. All right. So this is going to sound silly. This is going to sound like a silly question. The blood samples are stored at a temperature and humidity controlled area within a facility near Wayne State University known as TechTown, correct?

**A. That's correct.**

Q. All right.

**A. TechTown is on Cass and Burroughs.**

Q. And you did -- as part of your responsibilities at the Biobank you've never obtained or otherwise sought a search warrant from a judge to be able to continue to store blood samples, true?

**A. True.**

Q. All right.

MR. ELLISON: I think that's it, sir. I apologize. It took a little longer than I had thought, but I really sincerely appreciate it. I hope -- I hope this was not an unpleasant experience for you and I appreciate your time today. With that, I'm going to tender the witness to Mr. Kennedy and if he's got any questions, then Mr. Level might have some questions too for you, but otherwise, sir, I appreciate your time today.

THE WITNESS: All right. Thank you, Mr. Ellison.

MR. ELLISON: Thank you.

MR. KENNEDY: Dr. Yancey, I just want to clear -- make a couple things clear for the record.

EXAMINATION

BY MR. KENNEDY:

Q When you get a request from the State of Michigan to pull samples, blood spots, they give you specific numbers to

pull, correct?

**A That's correct.**

Q They don't just ask to pull random numbers, correct?

**A Correct.**

Q So in one of the hypotheticals that Mr. Ellison asked with Dr. Shah saying pull ten samples, if you didn't get specific numbers for those samples to pull, you wouldn't pull anything, correct?

**A That's correct.**

Q All right. Okay. I just wanted to clear that up.

MR. KENNEDY: I have nothing further, unless Mr. Levin does.

MR. LEVIN: I do not.

THE WITNESS: Who is Mr. Levin's representation? I missed that earlier and I want to ask that question before I leave.

MR. KENNEDY: He's from the Attorney General's Office.

THE WITNESS: Okay.

MR. ELLISON: The joke would be, of course, there's no halo behind his head right now, right? So ha, ha, ha. Anyway, I have no further questions at this point right now either. Again, Dr. Yancey, I sincerely appreciate your time today and I appreciate your forthrightness. This concludes the deposition going forward.

THE WITNESS: Thank you.

(At 1:56 p.m., deposition concluded)

-0-0-0-

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 31

## Historical Newborn Screening Pamphlets

## *Is there anything else I need to do?*

**ASK** Hospital staff or your midwife if newborn screening was done.

**BE SURE** The hospital or midwife and your baby's health care provider have the right phone number and address to reach you.

**CHECK** With your baby's health care provider or midwife about the NBS results.

**FOLLOW** Directions from your baby's health care provider if more tests or medical appointments are needed.

50th ANNIVERSARY

***1965-2015***

***50 years of saving babies!***

# Would you like to learn more?

**Please talk to your baby's health care provider or contact us by:**

**Telephone:**
1-866-673-9939 (toll-free)

**Fax:**
517-335-9419

**Email**
newbornscreening@michigan.gov

MICHIGAN Newborn Screening

P.O. Box 30195
Lansing, MI 48909

**www.michigan.gov/newbornscreening**

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5/15

# Michigan Newborn Screening

*50 years of saving*

# BABIES

***Learn about blood spot screening…***

## What is Newborn Screening (NBS)?

NBS is a program that screens all babies at 24-36 hours of age for rare but serious disorders. Michigan law requires newborn screening to make sure that babies who need treatment are found early. As part of newborn screening, your baby is checked for hearing loss and signs of critical congenital heart disease. A few drops of blood are also taken from your baby's heel to fill spots on a filter paper card. The card is sent to the State Newborn Screening Laboratory where blood spots are tested for over 50 different disorders that benefit from early treatment. This pamphlet describes newborn blood spot screening.

## My baby seems really healthy. Is NBS still needed?

**YES!** Whether your baby is born in a hospital, non-hospital setting or at home, screening should be done. Most babies with these disorders seem healthy at birth but can become very sick in a short time. If not treated early, serious health problems, severe developmental delay and even death can occur. NBS is the best way to find nearly all babies with these disorders as early as possible.

## What happens if screening suggests a health problem?

The NBS Follow-up Program will alert your baby's health care provider. You will get a call about what to do next, but it does not always mean your baby will have a problem. A second screening test may be needed.

## What are the disorders?

In Michigan, blood spot screening looks for over 50 disorders that may affect:

- Blood cells
- Brain development
- How the body breaks down nutrients from food
- Lungs and breathing
- Hormones
- How the body fights infection

Congenital hypothyroidism, sickle cell disease, and cystic fibrosis are some of the most common disorders. For a complete list, visit: www.michigan.gov/newbornscreening. NBS may also find some babies who are healthy carriers of these disorders.

## What happens if my baby has one of these disorders?

Help is available if your baby is found to have a disorder. Treatment usually begins early and continues through life. Each year NBS finds about 280 Michigan babies with these medical disorders.

## How is the cost of NBS covered?

If your baby is born in a hospital, the cost is part of the hospital charge. If your baby is born in a non-hospital setting, the NBS card must be purchased online at www.michigan.gov/nbsorders or by calling 1-866-673-9939. Some home births may qualify for a free screening.

## What happens to my baby's blood spots after screening?

All of the blood spots are not always needed for screening. The lab saves one full blood spot for future use by you or your child, if it is ever needed. The remaining blood spots are sent for permanent storage.

Remaining blood spots from newborn screening may be made available for future medical research with a parent's consent. To learn more, please read the Michigan BioTrust for Health pamphlet or visit www.michigan.gov/biotrust.

State law allows you to ask that a second blood spot sample be taken for your safekeeping. If you would like a second sample, please talk to your health care provider.

Forms are available if you want your child's blood spots destroyed after newborn screening is complete. Please call 1-866-673-9939 for more information or visit www.michigan.gov/newbornscreening.

## *Is there anything else I need to do?*

**ASK** The hospital staff or your midwife if the newborn screening sample was taken.

**ENSURE** The hospital, midwife and your baby's health care provider have your correct address and phone number to reach you if needed.

**CHECK** With your baby's health care provider or midwife about the NBS results.

**LISTEN** To your baby's health care provider and follow directions if more tests or medical appointments are needed.

## *REMEMBER…*

## *Newborn Screening Saves Babies!*

# Would you like to learn more?

**Please talk to your health care provider or contact us by:**

**Telephone**
Toll-free: 1-866-673-9939

**Fax**
517-335-9419 *or* 517-335-9739

**Email**
newbornscreening@michigan.gov

Newborn Screening Program
P.O. Box 30195
Lansing, MI 48909

**www.michigan.gov/newbornscreening**

Michigan Department of Community Health
MDCH
Rick Snyder, Governor
Nick Lyon, Director



50,000 printed at 3.0 cents each with a total cost of $1,745.50

9/14

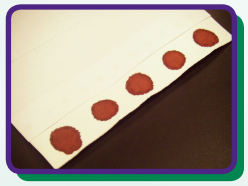
# Michigan Newborn Screening

## *saves*

# BABIES

## *Learn why your baby is screened…*

## What is Newborn Screening (NBS)?



NBS is a program that screens all babies for many serious medical conditions. A few drops of blood taken from your baby's heel are used to fill five spots on a filter paper card. After the blood is dried, the card is then sent to the State Newborn Screening Laboratory for testing.

Michigan law requires newborn screening to ensure that babies who need treatment are found early.

Whether your baby is born in the hospital or at home, NBS should be done between 24 and 36 hours after birth.

## My baby seems really healthy. Is NBS still needed?

**YES!** Most babies with these medical conditions seem healthy at birth but can become very sick in a short time. If not found early, many of the conditions can cause serious and permanent health problems, severe developmental delay and even death.

## What happens if screening suggests a health problem?

The Newborn Screening Follow-up Program will notify your baby's health care provider. You will get a call telling you what to do next. If you get a call from your baby's health care provider, it does not always mean that your baby has one of the medical conditions. A second screening test may be needed.

## What are the medical conditions?

In Michigan, NBS looks for over 50 conditions that may affect:

- Blood cells
- Brain development
- How the body breaks down nutrients from food
- Lungs and breathing
- Hormones
- How the body fights infection

For a complete list of conditions, visit: *www.michigan.gov/newbornscreening*

## What happens if my baby has one of these conditions?

If your baby has one of these conditions, there is help.

Treatment usually begins early and continues through life. Each year about 280 Michigan babies with these medical conditions are found by NBS.

## How is the cost of NBS covered?

If your baby is born in a hospital, the cost is part of the hospital charge. If your baby is born at home, the NBS kit must be purchased. If you do not have insurance or are unable to pay, NBS should still be done. Please call 1-866-852-1247 to see if you qualify for a free screening.

## What happens to my baby's blood spots after screening?

All of the blood spots are not always needed for screening. The lab saves one full blood spot for future use by you or your child, if it is ever needed. The remaining blood spots are sent for permanent storage.

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1/14

# Michigan Newborn Screening

*saves*

# BABIES

*Learn why your baby is screened…*

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The Newborn Screening Follow-up Program will notify your baby's health care provider. You will get a call telling you what to do next. If you get a call from your baby's health care provider, it does not always mean that your baby has one of the medical conditions. A second screening test may be needed.

## What are the medical conditions?

In Michigan, NBS looks for over 50 conditions that may affect:

- Blood cells
- Brain development
- Hearing
- How the body breaks down nutrients from food
- Lungs and breathing
- Hormones
- How the body fights infection

For a complete list of conditions, visit: *www.michigan.gov/newbornscreening*

## What happens if my baby has one of these conditions?

If your baby has one of these conditions, there is help.

Treatment usually begins early and continues through life. Each year about 280 Michigan babies with these medical conditions are found by NBS.

## How is the cost of NBS covered?

If your baby is born in a hospital, the cost is part of the hospital charge. If your baby is born at home, the NBS kit must be purchased. If you do not have insurance or are unable to pay, NBS should still be done. Please call 517-241-5583 to see if you qualify for a free screening.

## What happens to my baby's blood spots after screening?

All of the blood spots are not always needed for screening. The lab saves one full blood spot for future use by you or your child, if it is ever needed. The remaining blood spots are sent for permanent storage.

Remaining blood spots from newborn screening may be made available for future medical research with a parent's consent. To learn more, please read the brochure on the Michigan BioTrust for Health or visit: *www.michigan.gov/biotrust*

Blood spots cannot be returned to you after newborn screening. State law allows you to ask that a second sample be taken for your safekeeping. If you would like a second sample, please ask your health care provider.

Forms are available if you want your child's blood spots destroyed after newborn screening is complete. Please call **1-866-673-9939** for more information or visit the NBS website at: *www.michigan.gov/newbornscreening*

## *Is there anything else I need to do?*

**ASK** The hospital staff or your midwife if the newborn screening sample was taken.

**ENSURE** The hospital, midwife and your baby's health care provider have your correct address and phone number to reach you if needed.

**CHECK** With your baby's health care provider or midwife about the NBS results.

**LISTEN** To your baby's health care provider and follow directions if more tests or medical appointments are needed.

## *REMEMBER…*

## *Newborn Screening Saves Babies!*

# Would you like to learn more?

**Please talk to your health care provider or contact us by:**

**Telephone**
Toll-free: 1-866-673-9939

**Fax**
517-335-9419 *or* 517-335-9739

**Email**
newbornscreening@michigan.gov

Newborn Screening Program
P.O. Box 30195
Lansing, MI 48909

**www.michigan.gov/newbornscreening**

Michigan Department of Community Health
MDCH
Rick Snyder, Governor
Olga Dazzo, Director



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12/11

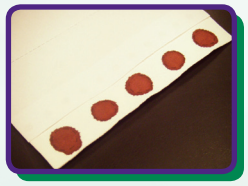
# Michigan Newborn Screening

## *saves*

# BABIES

## *Learn why your baby is screened…*

## What is Newborn Screening (NBS)?



NBS is a program that screens all babies for many serious medical conditions. A few drops of blood taken from your baby's heel are used to fill five spots on a filter paper card. After the blood is dried, the card is then sent to the State Newborn Screening Laboratory for testing.

Michigan law requires newborn screening to ensure that babies who need treatment are found early.

Whether your baby is born in the hospital or at home, NBS should be done between 24 and 36 hours after birth.

## My baby seems really healthy. Is NBS still needed?

**YES!** Most babies with these medical conditions seem healthy at birth but can become very sick in a short time. If not found early, many of the conditions can cause serious and permanent health problems, severe developmental delay and even death.

## What happens if screening suggests a health problem?

The Newborn Screening Follow-up Program will notify your baby's health care provider. You will get a call telling you what to do next. If you get a call from your baby's health care provider, it does not always mean that your baby has one of the medical conditions. A second screening test may be needed.

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- Hearing
- How the body breaks down nutrients from food
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Forms are available if you want your child's blood spots destroyed after newborn screening is complete. Please call **1-866-673-9939** for more information or visit the NBS website at: *www.michigan.gov/newbornscreening*

The Michigan Department of Community Health wants to help your baby get an early start on the road to good health. When your baby is born, important steps are taken to detect rare but serious disorders. Using just a few drops of your baby's blood, the Michigan Newborn Screening Laboratory performs screening tests to check your baby for these disorders. If not detected early, these conditions can cause mental retardation or serious health problems and even death. That is why the Michigan Department of Community Health tests every baby born in Michigan.

## *My baby seems really healthy. Are these screening tests really necessary?*

Absolutely. Experience has shown that newborn screening is the only reliable way to find babies with these disorders early enough to prevent mental retardation or early death. Most babies with these disorders appear healthy at birth, but the special screening tests can identify problems before a baby gets sick.

# What are the disorders?

### Amino Acid Disorders

Argininemia
Argininosuccinic acidemia
Citrullinemia
Citrullinemia type II
Homocystinuria
Hypermethioninemia
Maple syrup urine disease (MSUD)
Phenylketonuria (PKU)
Benign hyperphenylalaninemia defect
Biopterin cofactor biosysnthesis defect
Biopterin cofactor regeneration defect
Tyrosinemia type I

### Fatty Acid Oxidation Disorders:

Carnitine acylcarnitine translocase deficiency
Carnitine palmitoyl transferase I deficiency
Carnitine palmitoyl transferase II deficiency
Carnitine uptake defect
Dienoyl-CoA reductase deficiency
Glutaric acidemia type II
Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency
Medium/short-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency
Medium-chain acyl-CoA dehydrogenase deficiency
Medium-chain ketoacyl-CoA thiolase deficiency
Short-chain acyl-CoA dehydrogenase deficiency
Trifunctional protein deficiency
Very long-chain acyl-CoA dehydrogenase deficiency

### Organic Acid Disorders:

2-Methyl-3-hydroxy butyric aciduria
2-Methylbutyryl-CoA dehydrogenase deficiency
3-Hydroxy 3-methylglutaric aciduria
3-Methylcrotonyl-CoA carboxylase deficiency
3-Methylglutaconic aciduria
Beta-ketothiolase deficiency
Glutaric acidemia type I
Isobutyryl-CoA dehydrogenase deficiency
Isovaleric acidemia
Malonic acidemia
Methylmalonic acidemia
Methylmalonic acidemia (mutase deficiency)
Multiple carboxylase deficiency
Propionic acidemia

### Endocrine Disorders:

Congenital adrenal hyperplasia (CAH)
Congenital hypothyroidism (CH)

### Hemoglobinopathies:

S/Beta thalassemia
S/C disease
Sickle cell anemia
Variant hemoglobinopathies

### Other Disorders:

Biotinidase deficiency
Cystic Fibrosis
Galactosemia

## *What happens if one of tests is positive (abnor*

A positive screening test does necessarily mean that your ba one of the disorders. In fact, babies have a slightly positive screen for a variety of reasons a second test is required. Any whose screening test suggests chance of having one of the di will be referred to a medical sp for confirmation of the diagno treatment. The Michigan Dep of Community Health will noti baby's health care provider wh contact you with instructions follow-up.

## *If my baby has one of t disorders, is there a cu*

Babies with these disorders ca be cured, just as eye color or l type cannot be permanently c However, the serious effects o disorders can be greatly reduc completely prevented if a spec or other medical treatments ar early. Most children grow and normally when early diagnosi followed up with appropriate care.

## *What happens to my baby's blood specimen after testing?*

Newborn screening blood samples are kept by the laboratory and may be used for medical research. Before any medical research is conducted, the blood sample is separated from all identifying information to protect privacy. You can ask to have your baby's sample destroyed if you don't want it used for research. If you have questions or concerns, please contact the Newborn Screening Program at 1-866-673-9939.

## *Can the blood be returned to me following the testing?*

No. However, state law provides you with the option of asking that a second sample be obtained at the same time as the newborn screening sample for your safekeeping. This second sample may be important to your family at a later date for identification purposes.

## *Is there anything I need to do?*

Ask... the hospital before you leave if the newborn screening sample was taken.

Check... with your baby's health care provider about the newborn screening results.

Listen... to your doctor and follow recommendations for any additional tests or medical appointments.

Retest... your baby before two weeks of age, if discharged from the hospital before 24 hours. It is recommended by the American Academy of Pediatrics that you take your baby for a retest before two weeks of age. The retest can be done at your birthing hospitals outpatient laboratory.

## *Any other questions?*

Please talk to your health care provider or contact us at:

Michigan Department of Community Health
Newborn Screening Program
P.O. Box 30195
Lansing, MI 48909

Telephone: 517-335-9205
Toll-free: 866-673-9939
Fax: 517-335-9419

Website: www.michigan.gov/newbornscreening
Email: mdch-newbornscreening@michigan.gov

To order additional brochures, please call 517-241-5583.

Michigan Department of Community Health
MDCH
Jennifer M. Granholm, Governor
Janet Olszewski, Director

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Revised February 2008

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# *Michigan Newborn Screening Program*

# A First Step to Your Baby's Health

The Michigan Department of Community Health wants to help your baby get an early start on the road to good health. When your baby is only a few days old, important steps are taken to detect rare but serious disorders. Using just a few drops of your baby's blood, the Michigan Newborn Screening Laboratory performs screening tests to check your baby for these disorders. If not detected early, these conditions can cause mental retardation or serious health problems. That is why the Michigan Department of Community Health tests every baby born in Michigan.

## *My baby seems really healthy. Are these screening tests really necessary?*

Absolutely. Experience has shown that newborn screening is the only reliable way to find babies with these disorders early enough to prevent mental retardation or early death. Since most babies with these disorders appear healthy at birth, the special screening test can identify these problems before a baby gets sick.

# What are the disorders?

### Amino Acid Disorders:

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Citrullinemia

Citrullinemia Type II

Homocystinuria

Hypermethioninemia

Maple syrup urine disease (MSUD)

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- Benign hyperphenylalaninemia defect
- Biopterin cofactor biosysnthesis defect
- Biopterin cofactor regeneration defect

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Carnitine palmitoyltransferase II deficiency

Carnitine uptake defect

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Glutaric acidemia type II

Long-chain L-3-hydroxy acyl-CoA de hydrogenase deficiency

Medium/short-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency

Medium-chain acyl-CoA dehydrogenase deficiency

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Short-chain acyl-CoA dehydrogenase deficiency

Trifunctional protein deficiency

Very long-chain acyl-CoA dehydrogenase deficiency

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S/Beta thalassemia

S/C disease

Sickle cell anemia

Variant hemoglobinopathies

### Other Disorders:

Biotinidase deficiency

Galactosemia

## *...iat happens if one of the tests is positive (abnormal)?*

A positive screening test does not necessarily mean that your baby has one of the disorders. In fact, many babies have a slightly positive first screen for a variety of reasons. If so, a second test is required. Any baby whose screening test suggests a high chance of having one of the disorders will be referred to a medical specialist for confirmation of the diagnosis and treatment. The Michigan Department of Community Health will notify your baby's health care provider who will contact you with instructions for follow–up.

## *If my baby has one of these disorders, is there a cure?*

Babies with these disorders cannot be cured, just as eye color or blood type cannot be permanently changed. However, the serious effects of these disorders can be greatly reduced or completely prevented if a special diet or other medical treatments are started early. Most children grow and develop normally when early diagnosis is followed by appropriate medical care.

## *When should my baby be tested?*

Be sure your baby is tested before you leave the hospital. If this is before 24 hours of age, the American Academy of Pediatrics recommends a second test before your baby is two weeks of age.

## *What happens to my baby's blood specimen after testing?*

Newborn screening specimens are kept by the department for 21.5 years and then destroyed. During this time, some specimens may be used for medical research. Before any medical research is conducted, all identifying information is removed from the blood specimen card to protect privacy. If you have any questions or concerns, please contact the Newborn Screening Program.

## *Can the blood be returned to me following the testing?*

No. However, state law provides you with the option of asking that a second specimen be obtained at the same time as the newborn screening specimen. You can keep this specimen at home with your baby's records or in another safe place. This second specimen may be important to your family at a later date for identification purposes.

## *Is there anything I need to do?*

- Make sure your baby is tested. Ask your doctor or hospital staff if a specimen was obtained for newborn screening and sent to the Michigan Department of Community Health Laboratory for testing.
- If your baby is discharged from the hospital before 24 hours of age, take him/her to your health care provider for a retest before your baby is two weeks old.
- Check with your pediatric health care provider about your baby's newborn screening results.
- Follow your doctor's recommendations for any additional tests or medical appointments.

## *Any other questions?*

Please talk to your health care provider or contact us at:

Michigan Department of Community Health
Newborn Screening Program
P.O. Box 30195
Lansing, MI 48909

**Telephone:** 517-335-9205
**Toll-free:** 866-673-9939
**Fax:** 517-335-9419

**Website:** www.michigan.gov/newbornscreening
**Email:** mdch-newbornscreening@michigan.gov

To order additional brochures, please call 517-241-5583.

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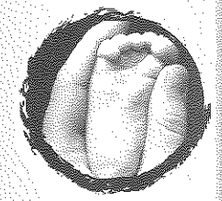
*Michigan Newborn Screening Program*

# A First Step to Your Baby's Health



***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 32

## 45 C.F.R. § 46.116 Effective June 23, 2005 to July 18, 2018

Code of Federal Regulations
Title 45. Public Welfare
Subtitle A. Department of Health and Human Services (Refs & Annos)
Subchapter A. General Administration (Refs & Annos)
Part 46. Protection of Human Subjects (Refs & Annos)
Subpart A. Basic HHS Policy for Protection of Human Research Subjects (Refs & Annos)

This section has been updated. Click here for the updated version.

45 C.F.R. § 46.116

§ 46.116 General requirements for informed consent.

Effective: June 23, 2005 to July 18, 2018

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990–0260.)

**Credits**
[70 FR 36328, June 23, 2005]

<Subpart effective until July 19, 2018.>

SOURCE: 56 FR 28012, 28022, June 18, 1991; 56 FR 28032, June 18, 1991; 59 FR 28276, June 1, 1994; 62 FR 16955, 17005, April 8, 1997; 62 FR 31669, June 10, 1997; 66 FR 3882, Jan. 17, 2001; 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a).; 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

**End of Document**

***Kanuszewski, et al v. MDHHS, et al.***
**USDC-ED No: 1:18-cv-10472**
**Honorable Thomas L. Ludington**
**Magistrate Judge Patricia T. Morris**

# EXHIBIT 33

## Deposition of Sonia Suter

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN, NORTHERN DIVISION

ADAM KANUSZEWSKI, et al,

Plaintiffs,

v File No. 18-cv-10472

HON. THOMAS L. LUDINGTON
MAG. PATRICIA T. MORRIS

MICHIGAN DEPARTMENT OF HEALTH and HUMAN SERVICES, et al,

Defendants.
/

VIDEO CONFERENCE DEPOSITION OF SONIA M. SUTER

Taken by the Defendants on the 8th day of February, 2021,

via Zoom, at 9:30 a.m.

APPEARANCES:

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Michigan Department of Attorney General
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(517) 335-7632

For Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey:
MR. JEREMY C. KENNEDY (P64821)
Pear Sperling Eggan & Daniels, PC
24 Frank Lloyd Wright Drive, #D2000
Ann Arbor, Michigan 48105
(734) 665-4441

RECORDED BY: Marcy A. Klingshirn, CER 6924
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Network Reporting Corporation
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1-800-632-2720

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Via Zoom Video Conference

Monday, February 8, 2021 - 9:32 a.m.

MR. LEVIN: Thank you for being here this morning. I'm going to assume you have a little bit more familiarity with depositions than some other people we've done this with, but all the same, I'm going to run through my basic outline points just so it's in there. So we're going to ask a handful of questions. Some of them we're going to know the answers to and they may sound a little silly, but that's just for our purposes. Don't worry too much about that. You may hear an attorney jump in with an objection. Just wait a moment. You will probably still answer, but we'll hash that out later among the three of us. If you don't know the answer to a question, that's perfectly acceptable. If you don't remember, that's perfectly acceptable. If you need us to rephrase or you don't understand something, we will clear that up. That's not a problem. I think that is my little background so I will jump in.

REPORTER: Do you solemnly swear or affirm the testimony you're about to give will be the whole truth?

MS. SUTER: Yup, I do.

SONIA M. SUTER

having been called by the Defendants and sworn:

EXAMINATION

BY MR. LEVIN:

Q What state do you currently live in?

**A I live in Maryland.**

Q All right. So I was looking at your CV and it looks like at some point you may have lived in Michigan. So have you ever lived in Michigan and for how long and approximately when?

**A I lived in Michigan for all of my childhood and a good part of the early part of my adulthood. I left Michigan in '97, I believe. I was out of Michigan for one year during a clerkship, but otherwise was in Michigan for a good part of my life.**

Q Have you ever been present in Michigan when a child was born?

**A Well, certainly. Children were born in the time I lived there, yes.**

Q Okay. So do you have any experience with medical professionals or staff seeking consent for research for the retained dried blood spots after newborn screening in Michigan?

**A As a patient or in any context?**

Q Any context.

**A Well, I was on a commission appointed by the Governor where we talked about this issue. But you're asking if I have any experience with health care professional? I guess I'm not sure precisely what you're asking me. I want to make sure I'm answering correctly.**

Q Okay. So I'm going to ask I think both because I'm going to circle back on that. So the question I guess right now is just personal experience, sort of -- not necessarily in a hospital room, but just for hopefully clarity sort of in a hospital room with somebody providing the form regarding consent for research uses for dried blood spots after newborn screening?

**A I have not had any personal experience as a patient in any kind of consent procedure regarding the collection of samples for newborn screening or storage.**

Q Do you have any experience with that not as a patient, in some sort of research context where you were in the room and somebody else may have been a patient?

**A No.**

Q Okay. So what was the -- you said you were on a commission. Can you tell me a little more about that?

**A Yeah. The Governor appointed a commission -- this is asking me to remember time -- somewhere around -- it was shortly before I left to come to D.C. and it included geneticists, researchers, M.D.s, lawyers, bioethicists to talk about various issues regarding genetics. I think it was called the Privacy in Progress Commission on Genetic -- Genetics Privacy and Progress Commission, something along those lines. It's in my CV. And essentially it was to just think about the various kinds of ethical/legal issues and what**

**sort of approach we would recommend for the legislature regarding genetics and the use of a genetic technology.**

Q Do you remember what the recommendation was?

**A Well, there were a lot of different recommendations so it would be hard to recall of them. You know, we recommended protections with respect to -- against genetic discrimination, protections of genetic privacy. There was a section on newborn screening.**

Q As it related just to newborn screening and the research uses following screening, do you remember anything in particular that came out from the commission?

**A Well, I do remember that I was the lone voice in saying that I thought we should require a consent for newborn screening and I could not get my colleagues to join me on that one. So for the actual process of the collection of samples. The premise was more -- as I recall at the time, more on the collection of samples and retention, less on the research aspects of it. I don't recall us focusing on that as much. But I've long been a believer that there should be consent at the outset of collection of samples and so I voiced that opinion, but I was in the dissent.**

Q Do you have any familiarity -- I guess currently are you familiar with the Michigan statutes regarding the newborn screening process?

**A Yeah. I mean, things changed quite a bit after I left so I**

**don't -- you know, I can't say that I have studied it deeply since, you know, 2014, but as I understand it, the research protocol has changed from an opt out to opt in approach in 2010 with respect to the research on the sample (inaudible).**

Q Okay. So just so we have this all cleared up, can you just explain a little about the difference between opt in and opt out?

**A Yeah. An opt out begins with a presumption that people will participate in whatever the procedure is, whether it's research or something else, and then to not be included one would have to affirmatively state that they did not want to participate as opposed to an opt in where the default would be we're not going to use the samples in the case of research unless you affirmatively say that you want to do that and unless you affirmatively consent.**

Q And just so I have this clear, do you know which one Michigan uses now?

**A They now have the opt in as I understand it starting in 2010 with respect to the research use of the samples.**

Q Are you at all familiar with the training and education that the Department of Health and Human Services does for health care staff regarding the retention for research purposes?

**A No, I'm not familiar with how they're trained, especially since it's changed.**

Q Are you familiar at all with anything -- or I'm going to

strike that and ask more clearly than "anything." Are you familiar with the training or education done by the Department regarding secondary uses after newborn screening in informing the public?

**A No; no, I'm not familiar with that. Again, as I said at the time that we were doing the work as a commission, we really weren't focused on that aspect so I don't know about the training.**

Q So I think you may have already answered this, but I'm going to drill down just a little bit. With regard to retention for research use after newborn screening, do you know if the Department of Health and Human Services requires parents to provide informed consent?

**A You're asking with respect to retention or with respect to research?**

Q Research. Sorry.

**A Okay. So with respect to research, my understanding is that it's an opt in approach so that it requires affirmative consent, but that retention is required, is mandatory, that the samples are retained for 100 years I believe.**

Q Do you know if that's the case for both anonymous and de- -- I'm going to strike that. I'll ask that better. I struggle with the word. Do you know if that's true for anonymized and de-anonymized research?

**A That's -- okay. So that's a good question. My**

**understanding is that opt in for both identified and de-identified, but I'm not 100 percent sure about that so I don't want to claim to know that.**

Q Should have used "identified." That rolls off the tongue much easier. And do you know if -- if a parent opts in initially, do you know if they have the ability to opt out later?

**A I believe they have the ability to opt out later with respect to the research.**

Q Do you know if an individual has the ability to opt out after they turn 18?

**A I believe they also have the ability to opt out after they turn 18. I'm not 100 percent sure of that, but I believe that's the case.**

Q Regarding the retained dried blood spots, do you know what sort of things the Department of Health and Human Services does to protect confidentiality?

**A The Michigan Department of Health and Human Service?**

Q Yes.

**A I don't know precisely what measures they take, but presumably -- I mean, I know they're used for various purposes, for quality assurance, sometimes cases where there needs to be identification of somebody who's deceased. But I would imagine that they have confidentiality provisions, but I don't know precisely what they used for that.**

Q So with the expert disclosure, we were given -- and I think you've referenced it -- an article you wrote in or is published in 2014. Are you familiar with that article with just that description?

**A Yes, I am.**

Q Do you know if the Michigan Department of Health and Human Services has made any changes to its policies or procedures regarding the retention of dried blood spots and use for research following newborn screening since that time? Since 2014?

**A I don't believe they have, but as I said, I haven't studied that to see whether things have changed since that piece was published.**

Q The article is still a generally accurate reflection of your opinion in this area?

**A Yes.**

Q So the article references the common rule. What is the common rule?

**A The common rule is a protection for human subjects, human participants in research which is defined somewhat narrowly, and it protects them in various ways with respect to the risks and benefits of research, with respect to consent, et cetera, to make sure that privacy -- the information is protected against privacy intrusions and also that people understand the procedures they're involved in.**

Q Do you know if Michigan treats retained dried blood spots as being subject to the common rule?

**A Well, my understanding is that it is not treated as part of the common rule.**

Q And that's in Michigan specifically?

**A Well, there was some debate about how newborn screening samples would be treated, whether they would be subject to the common rule and then for a period sort of generally they were, and then with the revisions of the common rule my understanding is that newborn screening samples were not treated as research if they're de-identified.**

Q So broadly, do you believe states should have an opt in approach to consenting to the use for retained dried blood spots for research?

**A Yes. I mean, I believe that states should have an opt in for all aspects of the process, from the point of collection of samples to the testing to the retention to the research.**

Q Do you know if Michigan has an opt -- I've asked this already, but just so it's all sort of together. Do you know if Michigan has an opt in approach for research uses for retained dried blood spots?

**A It now has an opt in for research uses through the BioTrust.**

Q Do you know for how long that's been the case?

**A Since 2010 is my understanding.**

Q So as I read your article, you advocate for separating

consent for storage of dried blood spots from newborn screening; is that correct?

**A In a perfect world you would separate out the issues, but I think they are integrated. I think that they influence one another, but they are separate questions and ideally should be addressed separately.**

Q Do you know if Michigan addresses those questions separately?

**A Well, my understanding is that there isn't an opt in for the actual testing so that they are just aggregated.**

Q But then is there a separate question for use of those retained dried blood spots?

**A My understanding --**

Q Does Michigan ask separately?

**A -- my understanding is that Michigan doesn't ask about the consent for the initial collection, testing and storage and then later asks for consent with respect to the research. So there's a separate process, but I guess it wouldn't be fair to say that there is consent in both places, so I guess I would make that distinction.**

Q Okay. But it is a separate process, whether or not it's a question both times?

**A Yup.**

Q So as I read your article as well, you advocate for states asking for general consent for storage of dried blood spots

for future research uses; is that correct?

**A Yeah. I mean, as I said, I believe that there should be a conversation from the outset about the collection of samples so people understand for what purposes they're being collected, both for testing, for conditions, the general categories of conditions, and then the retention and then potential uses for research.**

Q How much information -- so I believe I'm pulling the term "general consent" from your article, so sort of what is general consent in the context of this process?

**A Right. So one of the tricky things when you're collecting samples for medical purposes that then may be later used for research purposes, you may not know the full scope of research purposes. And so the consent can't be this sort of detailed, informed consent that you might offer somebody if they were coming in for a particular research protocol. Somebody comes in, says, "Give me samples. I want to test for X, Y, and Z." You could really give them a full sense of what it is you're going to be exploring through the research protocol. When you're collecting samples that will be stored for future research uses, it's virtually impossible to describe the scope but you could seek general consent for those future research uses. Potentially you could describe broad categories. I mean, how that would work could vary, but you could give people the option to say**

**generally I'm in favor of research, but I would like not -- certain kinds of research not to be included. But it can't be the kind of detailed consent that you would do for a very specific research protocol.**

Q Have you reviewed the form of the information Michigan gives to parents at the time they ask for consent for research uses?

**A I have not seen that.**

Q Why would it be problematic to ask for that fully informed consent as we've sort of described it here at the time it -- I'm going to rephrase that. Why would it be problematic or difficult to seek that as we've described it, more fully informed consent, at the time that Michigan currently seeks consent for its research uses for retained dried blood spots?

**A If I understand your question, you're asking why can you not get detailed informed consent at the moment you collect the samples. I think simply because the state or whatever research entity seeking that consent wouldn't know the full scope of research that they're planning in the future, right. If this is consent for future uses and you don't yet know what the protocols are, you can't offer detailed information. You could potentially depending on what the entity is, in this case BioTrust. You could describe categories of research that you plan to pursue. But just**

**simply because you're talking about future uses, not all of which would be known, it would be hard to offer the fully detailed information for a fully detailed, informed consent.**

MR. LEVIN: So I can pull up and share the article if this passage doesn't make sense out of con- -- it's not even full passage -- if the question does not make sense without -- without the article up. So I will just let everybody know that.

A **I have the article, too, if you want to tell me the page number.**

Q I have it on -- well, so I -- I have it on page 41, but I don't know because I don't have it with the -- the listed is 700, so I don't know what page that works out to, although I can tell you in just a moment.

MR. LEVIN: And then Phil or Jeremy, if you want me to share this.

Q It looks like it would be 768. But there's a reference to it being counterproductive to privacy interests to obtain informed consent for long term storage of dried blood spots and I wanted to ask why it would be counterproductive to privacy interests?

A **Okay. Yeah. This is out of -- I do want to know the context in which that sentence happened.**

Q Sure.

A **So 768 doesn't look like it has it.**

Q All right. I will find it.

**A But I'm just scanning, so perhaps I'm missing it. Okay. I think I see what you're talking about. Right. So what I'm saying is that if you wanted to go back for every single research protocol, then you would -- it would be mostly focused on the expense to try to go back. So instead of asking sort of general consent up front and going back for every single research protocol, you would then have to go back to everybody, you'd have to keep the samples identifiable, and so that would make it less protective for privacy interests. If you want to be able to locate the individuals for every single study, then it potentially doesn't offer the protections of keeping them in more of a de-identified form, but also an expensive process which is why I sort of advocated an in between -- that's representing the very sort of strong privacy autonomy extreme as opposed to the strong research extreme and I was trying to find something in the middle.**

Q Is it important to allow children to decide for themselves whether they want their dried blood spots retained after reaching the age of majority?

**A I believe so, yes.**

Q So my version of the article is running something so that I can search it, but there's another reference to Michigan's approach to informed consent for research on retained dried

blood spots as being, the quote is "commendable." I have that on page 52, but it's running it so I can't get the 700-page number. I'm going to ask why do you say that, but I can wait until we can pull up that passage a little bit more clearly.

**A I mean, I don't think I need to see the actual passage. I liked the fact that Michigan moved from the opt out to the opt in for the research piece of it. I thought that was appropriate to seek affirmative consent and that it would be a default against doing research unless there was affirmative consent on the part of the parents.**

Q There was also some discussion -- and I'm not sure it's in the same place -- but about this charitable trust model. Do you know if that's what Michigan has?

**A Well, at the time that's what I understood they had. I don't know if they still do.**

Q What kind of interests have to be balanced when designing a system for obtaining informed consent for retention and research of dried blood spots?

**A Right. So with respect to the research side, I think obviously there's the public benefit of doing research, of understanding diseases, of having a collection of samples that represent the population. If you didn't require any consent, then you wouldn't have any kind of consent bias. So if you really just cared about research, you wouldn't ask**

anybody for any consent and you'd just do whatever you wanted with the samples and get whatever information you wanted. But you have to balance that against the privacy and autonomy interests of the family both with respect to what information about individuals could be gleaned, but also I think there's an autonomy interest in deciding what you want your biological material to be part of, what kinds of research protocols you want to support or not support. And these samples could be used in all manner of ways and people may have personal objections to certain kinds of research, certain sorts of uses and so I think there are strong autonomy interests.

I also think the privacy interests are getting greater as technology advances because even if you de-identify samples, the truth is it is going to be increasingly difficult to truly anonymize samples. We're discovering that it is very -- there are complicated ways you can do this, but it's getting easier to try to determine whose sample belongs to whom. And since our genetic information contains so much information about us -- not everything, but a great deal about us -- having control over who has access to that is I think a really important privacy interest.

And they come into conflict; right? There's a tension between the two and that's what my piece tried to

**grapple with. How do we best balance these two public goods that we should both care about? And I sort of argued against going entirely in one direction, the totally pro-research direction, or the totally pro-privacy and autonomy but seeking some sort of balance between the two of them.**

**And I guess I would add one other thing which is that I think when you're trying to balance those sorts of interest, I think you have to consider this in the context of samples that have been mandated to be collected which is a very unusual thing for the state to do, to require people to hand over samples, biological material. We do it in the military, we do it with people who have been arrested in some states or convicted of crimes. But to do this with the entire population is really something and then to have those samples on hand for 100 years potentially for use of research is problematic.**

Q So regarding only the research purposes, or the possible research purposes and the consent for those purposes, how well do you feel Michigan's approach balances these competing interests?

**A With respect to the research part it adopts the opt in which I like, but that just deals with the research piece. It doesn't deal with the storage, it doesn't address potential other uses, would the samples be shared with others or not,**

**what restrictions are there against that, and the fact that the samples were collected in the first place. As I said in my piece, I think that if you're collecting samples for disease detection, it's a lot more persuasive when the only diseases you're testing are ones for which there's treatment and serious irreversible harm if it's not identified early. But testing has really broadened in scope and so we're now getting a lot of information that could be problematic. So that piece I -- as I said, since I was on that commission, I've tried to push against the mandated collection in the first place and I feel more strongly as testing has changed.**

Q What kind of problematic information is potentially available?

**A So when newborn screening first began, I mean, there were problems with it and I won't address all of it, but eventually it became a mechanism to test for PKU and that made sense to do that in all states because this was a heritable condition that could lead to irreversible intellectual disability and there were things that could be done if identified early. And in the early days, they didn't actually have the treatment protocol very well worked out, but today we know how to do this. And there are some other diseases like that where you can identify a condition, you can offer preventive care or treatment if -- the states aren't always good at providing that, but at least there's a**

theoretical option to prevent the disease. But now that we're expanding towards testing for conditions that are not treatable or conditions that we don't fully understand whether they're serious or not, you go down this path of identifying children who might be sick, might not be sick. Parents worry about this, there's false positives.

We're starting to move towards a model of newborn screening that isn't about trying to protect the well-being of the child, but that's now focusing on other interests like giving parents reproductive information or giving information for the state. We could maybe identify a condition, we don't know if it's really serious, but we could study the natural course of that. But parents now, there have been -- there has been some -- some study on the potential impact on the parent/child relationship when a child is sort of a patient in waiting, maybe sick, maybe not sick, we don't really fully understand.

I think newborn screening should be limited to very clear identification of conditions that manifest early in childhood and that are treatable and we have gone well beyond that. And I think we will soon move towards using whole genome sequencing where we're just getting all sorts of information about newborns. And I think, you know, as a former genetic counselor, I feel very strongly about people making informed choices about what information they want to

**learn about themselves with respect to genetics. And this is going well beyond trying to identify information that offers the possibility of preventing illness. It goes beyond that.**

Q Is that more of a national trend or is that specific -- those concerns, are those sort of a national trend or are they specific to Michigan?

**A It's a national trend. It's a national trend.**

Q Do you know how applicable they are to Michigan right now?

**A You know, I haven't looked at exactly how many diseases, but Michigan -- I mean, I was part of another commission that recommended trying to come up with more uniform testing protocols because one problem was that, you know, you could not be tested for a serious disease in one state and a child could die in that state, but then in the other state they could be identified. So there was a move towards unifying or establishing a more uniform standard of testing but I think that some of the -- we had debates within that committee about how to handle what diseases are included and I think that one could argue that some of the protocols have pushed too much towards including some diseases that aren't clearly clear pathologies or that don't have treatments. And so that is part of a national trend and I imagine that Michigan -- I haven't looked at how many, but I imagine that they are, probably have at least 59 conditions or whatever**

**the now the minimum is. But I don't know the precise number.**

Q Are there disadvantages to seeking consent for research purposes of dried blood spots before newborn screening?

**A You mean seeking it during the prenatal period, for example?**

Q Yes.

**A I mean, in a perfect world, in a perfect world I would love it all to happen in the prenatal period because people would not be worn out after having just given birth. They would be thinking ahead. They would have more time to contemplate the choices. But the truth of the matter is a good percentage of women don't get the prenatal care and are first seen when they give birth. And so we're going to miss a lot of people in the consent process if we do it then. So if we had a better system overall with respect to delivery of health care, if we could get everybody in for prenatal care, that would be the optimal time, but it's not realistic given the system we have.**

Q Is retention of dried blood spots necessary to follow up and ensure appropriate intervention for affected children?

**A Yeah. I don't know if you need them for 100 years, but one could argue that there is value in having them for follow-up, yes, for some period of time.**

Q Is retention for some period of time necessary to make confirmatory diagnoses?

**A Well, I mean, one could get the sample from the child itself, but if you're trying to do some confirmation before you call in to have a child tested -- you know, remember, of course, it's a screening so to do the true diagnostic testing, there's going to need to be follow-up. So at some point you bring the family back in to do the follow-up testing to confirm the positive screen result.**

Q Is retention of dried blood spots necessary to ensure the accuracy of the newborn screening itself?

**A You mean for like quality assurance and to make sure that your protocols are working efficiently? I guess one could argue that retention for some period is also valuable for that.**

Q A moment ago you made a reference to a different sort of -- between a screening test and a diagnostic test. Can you expand on that a little?

**A Right. So newborn screening isn't trying to diagnosis everybody who has a condition and this is part of my concern about testing too broadly. Inevitably you're going to get false positives and false negatives because it's not by definition diagnostic. It's trying to cast a wide enough net that you catch the infants that have -- are likely to have particular conditions and then further testing can be offered. So when you're trying to do population testing, often you have to rely on something like a screening test**

**that can't be as precise. A diagnostic test is really, depending on what the condition is, you might be looking at metabolites, you might be looking at genetic variants, but you're actually trying to determine whether this individual actually has the condition that they were screened positive for.**

Q Do you know -- I'm switching gears a little bit here. But do you know when Michigan does its newborn screening, what kinds of information the process reveals?

**A I'm not sure what you mean by what kinds of information. I mean, it identifies -- it uses different kinds of tests, right. So as I understand, the move has gone from towards the tandem mass spectrometry, so you're looking at these in the top metabolite variants for certain things, but there are other tests that are a bit different. So I guess I'm not sure what you're asking exactly. What --**

Q Sure. So relatedly, but I'll ask a different way. Do you know if Michigan is doing full genome sequencing?

**A I don't believe they are. Not -- not as a routine. I mean, whether they're part of some research protocol because some entities are doing research on the possibility, but not as a matter across the population. I don't believe they're doing whole genome sequencing.**

Q Okay. So then let's -- we're getting a little bit out of my depth in terms of the science they do, but just for purposes

of this question. If somebody runs a test on a blood sample on a mass spectrometer, do you know what kind of information that test reveals?

**A So that's also beyond my pay grade because I studied genetics and that's metabolites. But my understanding is that they're looking at variants that differ from normal amounts of metabolites. And because basically a lot of these conditions there are some ki- -- often genetic deficiency that doesn't allow enzymes to work properly, and so there are certain kinds of proteins that don't break down in the way they should and so you would see too much of certain metabolites. And so they're looking for that. It's not perfect, but they're trying to see sort of variants from normal and identify it, flag those.**

**But as with whole genome sequencing, what ends up happening is that you might use this test to look for certain kinds of things, but then you might find other kinds of variants and then you're not always sure what those other variants mean. And that's where I worry about, you know, using those variants as a way to identify an infant as potentially having a condition when we don't even know what it means to have that variant. This is becoming a real issue in genetics and also with the tandem mass spectrometry that we end up in this kind of very gray zone where we create a lot of stress because we don't really know what**

**things mean. We just know that they're variants, but there are variants that can be normal and not clinically significant and some that can be pathological and we don't always know which is which.**

Q Do you know, and you may not, if the sample is run through a mass spectrometer, how many metabolites does that reveal? Or am I -- if I'm even asking that correctly?

**A Yeah. I don't know exactly how many. I mean, my understanding is they're running it to look for certain ones, but they may see variants in other areas. So I'm not going to even pretend to know how many.**

Q Do you know how many tests make up the newborn screen? The newborn screening process?

**A I -- you know, I don't know what the number is right now. I think the basis -- I forget even what I said the base was because it's been moving. And I talked to a colleague a few months ago, but now I'm not remembering exactly what the number is, but I think it's around 59. This is terrible. It's in my piece, the number I gave. But that's 2014. That's probably outdated.**

Q Is that 59, is that different conditions they are looking for or is that individual -- like the mass spectrometer, is that individual processes these samples may go through?

**A Different conditions they're looking for, many of which they'd identify through the tandem mass spectrometer, but**

**others that might be identified differently.**

Q Okay. My question -- and I'll try to ask it a little more clearly. Do you know how many processes they may go through in looking for those? So is it one mass spectrometer test? Is it two? Is it a mass spectrometer and something else? How many of those processes?

**A I think it's the mass spectrometer and something else but I'm not going to claim to know exactly what the different processes are.**

Q All right. Thank you. Switching gears back to Michigan's policies. Do you know how many newborn screens are done in Michigan annually?

**A Unh-unh (negative).**

Q So just because we're recording, that's "no"?

MR. ELLISON: Hold on. Hold on a second. Professor, I hate to do this to you. You've got to say "yes" or "no" because "uh-huhs" and "ums" don't pick up real well, so --

THE WITNESS: So sorry.

**A No, I do not know.**

Q And that was one of the things I should have mentioned off the top. Normally that makes my little speech. So my apologies.

**A That's all right. Yeah, that -- I should have thought of that.**

Q I was going to say "uh-huh." You know, I was going to do the same thing in response.

MR. ELLISON: I was going to say we do it every -- every deposition one of us does it, even the lawyers, so don't lose any sleep over that. So go ahead, Aaron. I'm sorry to interrupt.

MR. LEVIN: Yeah, I was going to say "uh-huh" to agree with Phil, so I needed to catch myself.

Q Do you know in Michigan who is responsible for providing information to parents regarding research of retained dried blood spots?

**A That -- actually I don't know the answer to that for sure because when I was in Michigan it was the responsibility of the hospitals that -- I was a genetic counselor and I had just a little bit of a role in getting to the hospitals and making sure they understood how to let the patients know about -- or to make sure that the hospitals knew about collection of samples. So I'm not sure who actually is the one that gets the consent for the opt in. I would imagine it's the health care professionals within the hospitals, but I don't know that.**

Q Should have asked this earlier. What is a genetic counselor?

**A A genetic counselor is somebody who works -- it has changed quite a bit since I was doing it. But often they work with**

**some other health care professional, an obstetrician, a pediatrician, they could be at a hospital, now they -- many of them work in labs, and their job is to educate patients about what sorts of testing is available, what it means; often they get family histories, in the case of obstetrics, pregnancy histories to identify any particular genetic risks; and then to describe to individuals what -- if they're in a clinical context, what kinds of testing is available, what the pros and cons of the testing are, and that help patients make choices that are consistent with their values and life plans. There's a strong non-directive ethos in genetic counseling which is sort of centered around this idea that people should be able to make choices about how they get genetic information and that it should be tied to their own values and so that the role of the health care professional should not be to push in a particular direction which may help explain part of my discomfort with the states pushing testing and requiring it. I think that really violates these strong norms in genetic counseling.**

Q We talked earlier about -- I believe your statement was something to -- it's not a quote, but I believe the thrust of your statement was in a perfect world, we would seek informed consent for research in the prenatal period. Is that a fair characterization?

**A Yes.**

Q Do you know if the Michigan Department of Health and Human Services has any sort of policies that prevent medical professionals from doing that?

**A Oh, I would hope not. I'm not aware of any policies that prevent that. In fact, my sense is that there's some encouragement to try to get that information out sooner rather than later.**

Q All right. So I am wrapping up, I believe, but I do want to ask -- so we were given an expert disclosure and it describes -- and this is also not a quote, but it represented that you will show some alternative methodology exists for obtaining consent in Michigan. What is that methodology?

**A Well, I believe that patients -- I mean, and I think there's real value in trying to do it in the prenatal period, but people should have the option in the newborn period if they haven't had a chance or haven't been consulted, but I believe that people should be given the choice as to whether or not they want to participate in the newborn screening in the first place. They should understand in a general sense what newborn screening is trying to do. I don't think they can list every single condition that's involved, but explain that this is a state run process to identify infants at risk for various conditions such as -- you can give a general description -- and give parents the opportunity to consent**

to that and that samples will be stored, and then ask the separate question about research. And so it should be an opt in for all aspects of the process in my view. But -- and the biggest reason that I argue for this is that I think that when you have a default from the outset that presumes people will be included in this process -- I realize the research is asked about later -- it does not create incentives to educate parents about what is happening and I actually think it undermines the goals of the state. If the state is trying to encourage testing and follow up, it is better for parents to understand that there is this protocol because most parents, vast majority of parents will say yes, but then they will understand what their child is being tested for and make sure that the testing happens and find out about follow up. But the system that presumes that has a default of not asking, the default is we're going to do it, there's no incentive to provide that information to parents outright. And what parents really want is education. And so if the state has to work a little bit harder to seek consent by educating parents, that's a net gain, I believe, for the system, for families, for autonomy and for the goals of identifying more infants. In states that have had opt in approaches, they've had very -- they've had better testing rates than in states that mandate ironically. So I believe consistent with the values of

**autonomy that we should be asking for affirmative consent from the outset about the collection of samples, the testing, the retention of samples and then the research, or other uses, right, if the samples are shared, whatever uses are put to those samples.**

MR. LEVIN: I think that is all I have at this point. I think just for Jeremy and Phil, I know we -- I'm pretty sure we've all been reading our own copies of the article, but I think we referenced it enough that I will mark it as an exhibit and circulate and have that attached as we go forward. But that's all I have at this point. So thank you for being here and I will pass it to Jeremy if he has anything.

MR. KENNEDY: I actually -- if possible if we could go off the record for a few minutes? I have a background issue I have to deal with in the other room.

THE WITNESS: Sure.

MR. LEVIN: Not a problem.

MR. KENNEDY: Thank you.

(Off the record)

MR. KENNEDY: All right. Good morning, Professor Suter. My name is Jeremy Kennedy. I'm the attorney for Dr. Antonio Yancey in his professional capacity.

EXAMINATION

BY MR. KENNEDY:

Q I just want to go over some background information. You've been obviously presented as an expert here. What is your educational background?

**A I have an undergraduate degree in English. Do you need me to tell you which schools or just general ed? I don't know how specific you want me to be.**

Q If you could just let us know what the degree is and where it's from?

**A Okay. I have a BA in English from Michigan State University; I have a master's of science in human genetics from the University of Michigan; I am ABD, all but dissertation, so I achieved candidacy, Ph.D. candidacy for human genetics also at the University of Michigan but didn't do the dissertation part; and I have a law degree from the University of Michigan as well. So educated entirely by Michigan public schools (inaudible).**

Q Okay. And you are currently a -- are you a professor at George Washington?

**A Yup. I'm a professor of law at George Washington University.**

Q And how long have you been at George Washington?

**A I started in May of 1999, so it's a long time, over 20 years.**

Q And prior to that were you in private practice or have you been in the academic field for the entirety of your career?

**A Pretty much the entirety of my career. I did do two summer internships at law firms, but then I clerked after I graduated from law school on the 2nd Circuit for Judge Walker, John Walker, and then I was actually planning to go into private practice, but had an opportunity -- I knew I wanted to go into academics, so I was invited to be a visiting professor at the University of Michigan where I taught for two years. And then I did a fellowship in bioethics and health policy through Georgetown and Hopkins for two years, and then started teaching at George Washington.**

Q And what is your specialty from a legal perspective? What are the primary areas of concern?

**A I teach torts, but I would say that's not my primary area in which I write, although some of -- when people in health law often write, teach torts because there is definitely overlap there. But my scholarship is primarily in the area of law and medicine, bioethics and law. I teach a course called one medicine which is bioethics issues in law and I teach a genex law course and I teach a course on assisted reproductive technologies. And I'm coauthor of two textbooks, one for genetics in law, and one for assisted reproductive technologies.**

Q Okay. And Mr. Ellison provided us your CV and list of publications. Is that up-to-date or is there anything that

has been published in the last --

**A I don't know which CV you have. I haven't sent him something in awhile, so I imagine that it needs to be updated. What is the last publication you have listed?**

Q Oh, give me a second. I have to pull it up. I --

MR. ELLISON: I have it right here just in case. The last CV I got from you would have -- I turned it over in January of 2020, so it would have been more than a year ago.

THE WITNESS: Yeah, so I would need to update certain things. I can pull up my own CV and tell you. Since then the genetics and law textbook has been published. Let's see. Career. I'm trying to find my most recent CV here. I have a piece in fertility and sterility that came out in the fall. I have a piece forthcoming on prenatal genetic testing and germline gene editing. Trying to do this off the top of my head. I don't know. I can for- -- also just send you my most recent CV if that would be helpful.

MR. ELLISON: Why don't you do that? Send it. I'll have Lisa connect with you to make sure that you can get it over to us and I'll forward it on to the rest of the attorneys. No problem.

THE WITNESS: Yeah. It's just hard to off the top of my head think of all the things. I've been doing a lot of writ- -- and I have a bunch of things forthcoming. So,

yeah, I'll send that to you to update it.

Q I just want to make sure we have the most up-to-date one and Phil said it's been a year, so if you can get that to him, he'll circulate that to us I'm sure and that would be fine. Have you testified as an expert previously?

**A I have not. Not in a deposition, no. I've worked on various commissions for developing policy, but I have not testified as an expert.**

Q Okay. And have you provided a written report for this case yet?

**A I have not.**

Q Do you intend to provide a written report?

**A We had not talked about that, so I hadn't been asked to.**

Q Okay.

**A And I would be willing if necessary, but I have no written agreement one way or another.**

Q Okay. And did you review anything regarding the Michigan BioBank system, the BioTrust system prior to this deposition?

**A I just looked briefly online about what, how it had changed and when exactly what was part of it. So a little bit, but not a great deal (inaudible).**

Q Okay. So are you familiar with the Michigan BioBank's requirements for research using dried blood spots for research? Actually, the Michigan Department of Health and

Human Service requirements for the use of the dried blood spots for research?

**A Do you mean that you must get an opt in? That there must be affirmative consent? Is that what you're referring to?**

Q I'm speaking generally. Are you aware of what requirements they have in order for the dried blood spots to be used for research?

**A Really I know primarily that they have to get the affirmative consent since 2010. I haven't looked at (inaudible).**

Q And are you aware of what steps have to be followed by researchers who want to use the dried blood spots?

**A I mean, it depends I'm sure -- I have not looked at the details of everything that they have to do, all the details. But I imagine they would have to comply -- if the samples are identified, they would have to comply with all the requirements for that. But I don't -- I haven't looked at anything specifically that the state required.**

Q Okay. And are you familiar -- do you know any of the directors of the Michigan BioBank?

**A I don't know the names of the directors. It's possible I do know them, but I suspect not. I don't know their names off the top of my head.**

Q Have you -- do you know or -- let me run through them real quick then. Do you know or have you ever worked with Dr.

Antonio Yancey who is the executive director?

**A Nope.**

Q Have you ever worked with or do you know Scott Jewell?

**A No.**

Q From the VanAndel Institute? How about Sonia Hassan?

**A No.**

Q Have you ever worked with or do you know Ed Goldman?

**A I do.**

Q And how do you know Mr. Goldman?

**A I met him when I was a law student and I worked a summer with him at the hospital counsel's office, and then we were on the commission together, the Michigan Privacy and Progress Commission, and we were also -- was Ed part of -- I can't remember if he was part of the newborn screening, the one, the ACMG one. I think he was part of that as well, but I'd have to double check that. But, so I've known him for years.**

Q Okay. Do you know when the last time you spoke with Mr. Goldman was?

**A We were really good about staying in touch until I had young kids, and then I was -- I just saw something recently, an e-mail. It's been awhile since we've had a conversation honestly. We were very good up until probably the early to mid-2000, like probably around 2004 is when I had my second child and then it seems like conversation just didn't stay**

**as good.**

Q Okay. So you were not (inaudible) this matter then?

**A I'm sorry. There was a funny sound.**

Q You haven't spoken with him about this -- about this case?

**A No, I have not.**

Q Okay. And then have you ever worked with or do you know Dr. Sandip Shah from Michigan Department of Community Health?

**A No.**

Q And the last board member, do you know or have you ever worked with Dr. Nigel Paneth, Michigan State University?

**A No; no.**

Q Okay. Professor Suter, are you aware of how many states have a newborn screening program?

**A Every state has a newborn screening program.**

Q And how many of those states require consent before the screening program is done?

**A I don't have the most recent numbers, but the majority in my understanding have an option to opt out either for religious reasons or sometimes for general reasons. So most newborn screenings work with an opt out approach.**

Q And that's for the screening itself, not for any subsequent use?

**A Yeah.**

Q Now do you know how many states store the samples afterwards?

**A I believe all states store samples. Some have explicit requirements about how long and some are sort of unclear on that.**

Q Okay. And I believe you indicated -- and if I misheard/misunderstood something, let me know -- that in your opinion there should be a limit on how long samples are stored?

**A I think there is an argument for keeping the samples long enough to do the validation, but I'm not sure you need to store them for 100 years. I haven't sorted out precisely what I think that limit should be.**

Q So somewhere between a couple months to do validation and 100 years is where we find the sweet spot?

**A I mean, I probably consider more than a couple of months, but, again, I haven't, you know, fully thought through the exact time period.**

Q Okay. And it also sounds like one of your major concerns is protecting the privacy of individuals; is that correct?

**A Privacy and autonomy interests, yes.**

Q Okay. Now what do you think since you're asked to provide an opinion here is the steps that should be taken to protect the privacy of the individuals when the samples are stored?

**A Right. So obviously you want to protect against access to those samples by any other entities than the state without consent of the parties. You would want to ensure that there**

**were protections against hacking and access. So, you know, access that is intentional and unintentional access you would want protections against that. To the extent possible that they would remain unidentified, although obviously for certain purposes if you were trying to do follow-up and confirmation, you'd need them to be identifiable for those purposes and that there would be limited access to the parties necessary for using the samples for their intended purposes.**

Q Okay. And from an autonomy standpoint, what do you believe is necessary to protect the autonomy of the individuals?

**A So that there is affirmative consent for the various purposes. So consent to the collection of the samples, consent to the testing, consent to the storage and to the research and/or other uses. So if there would be any sharing of the samples, anything else that would happen to the samples after that point.**

Q And I believe you indicated that it's more difficult to get consent on anything other than a broad sense if the samples remain de-identified; is that correct?

**A Well, I mean, are we talking about for research? Are we talking about consent with respect to which aspect?**

Q I'm sorry. For research purposes after the samples are collected and stored.

**A Yeah. I think the difficulty with detailed informed consent**

**for future research uses goes beyond whether they're identified or not. It has to do with the -- at the time you collect the samples you don't know what those future research uses might be. Now, you could go back and ask individuals if you retained the samples if you had them identifiable, you could go back for every research protocol and seek consent from everybody for every single research protocol. I don't think that's very practicable. If the goal is to do research down the road, I think that's expensive, costly, and frankly impossible in some cases. You wouldn't be able to track down the individuals.**

Q So it's a balance between protecting the privacy and providing autonomy down the road if you're doing something like this; is that fair?

**A Yes, which is why I think the sort of general consent up front perhaps with a refusal for certain kinds of protocols would be the best way to optimize the tensions at work here or to balance the function.**

Q And if you allow parents the option to have the samples destroyed, that also protects the autonomy, would it not?

**A Yes; yes. To allow the parents to have the samples destroyed at some point, yes, that would protect autonomy interests and whether those samples are potentially accessible by various parties.**

MR. KENNEDY: That's actually all I have today.

Keep it short this time.

MR. ELLISON: I have one -- I just have one question to follow up just to make sure the scope of what you're being called upon to testify to is clear.

EXAMINATION

BY MR. ELLISON:

Q You've had a lot of questions today about all sorts of aspects of this but you would confirm that as part of your understanding, as part as being an expert in this case, that you've not been called upon to review whether the level of informed consent that was obtained or attempted to be obtained by the state as part of either -- as part of the research purposes is legally sufficient or is -- in fact, or is not informed consent; correct?

**A Correct.**

Q And the scope of the testimony that I am seeking to -- that I have spoked to you about to serve in this capacity is about the use of an opt in based system as opposed to an opt out based system for newborn, residual blood spot newborn research spots that are left over essentially?

**A Yup; yes.**

Q Yes. And you're not being called upon -- you have not been called upon to ask about the constitutionality, the legality or the policy, the policy preferences of the state or should be preferences of the state as it applies to these

circumstances; correct?

**A That is correct.**

MR. ELLISON: Thank you very much, professor. I appreciate your time today. I don't know if these two guys have any other follow-ups. They get one more round with you if they got anything else, but I don't have anything else for you today and I thank you very much. I'm going to call you right afterwards, too.

THE WITNESS: Sure. Okay.

MR. LEVIN: I do not have anything else. Thank you for your time today.

THE WITNESS: Sure. All right. Take care.

MR. KENNEDY: I'm all set. Thank you.

MR. ELLISON: All right.

(Deposition Exhibit A marked)

(Deposition concluded at 10:32 a.m.)

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