UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI et al.,

Plaintiffs,

v.

SANDIP SHAH et al.,

Defendants.
_____/

Case No. 1:18-cv-10472

Honorable Thomas L. Ludington
United States District Judge

OPINION AND ORDER (1) GRANTING PLAINTIFFS' MOTION FOR RECONSIDERATION, (2) DENYING DEFENDANTS' MOTION FOR RECONSIDERATION, AND (3) VACATING IN PART PRIOR OPINION AND ORDER

The parties have filed cross-motions for reconsideration of this Court's July 2021 Order. As explained hereafter, Plaintiffs' Motion for Reconsideration will be granted, Defendants' Motion for Reconsideration will be denied, and the July 2021 Order will be vacated in part. In this way, summary judgment will be granted in Plaintiffs' favor for all but five of their claims for which triable questions of fact remain. Two Fourteenth Amendment claims remain regarding five children, and three Fourth Amendment claims remain regarding all the children.

I.

This case involves a § 1983 action arising from constitutional violations concerning Michigan's Newborn Screening Program (NSP). The following facts have been truncated to address the issues discussed in this Order. For a fuller disquisition, see generally *Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 750–58 (E.D. Mich. 2021).

A.

Under Michigan's NSP, established in the 1960s, the State of Michigan and its agents prick the heel of nearly every newborn to collect five or six drops of blood with a Dried Blood Spot

(DBS) collection card.[1] *Kanuszewski v. MDHHS*, 927 F.3d 396, 403–04 (6th Cir. 2019). The Michigan Department of Health and Human Services (MDHHS) then tests the blood for 58 disorders. ECF No. 135-11 at PageID.2179. In roughly 60 years, Michigan has diagnosed those disorders in about 0.2–0.25% of its newborns. *See* ECF No. 147-2 at PageID.4243. The relevant Michigan statute waives informed consent for these tests only.

As the Association of Public Health Laboratories[2] (APHL) explains as *amicus curiae*, every state and territory in the United States has an NSP. *See* ECF No. 146 at PageID.4150. ("More than 98% of all children born in the United States receive [newborn blood screening]."). Although they are not profitable for "state governments," *see id.* at PageID.4152, NSPs allow states to "research" the "biomarkers" of "nearly the entire population," including their "DNA, RNA, proteins, metabolites, and evidence of exposures to environmental or infectious agents," *id.* at PageID.4157, 4159. To that end, the APHL adds, "retention and storage of residual DBS specimens is crucial." *Id.* at PageID.4142.

According to the APHL, every state should—but does not—require "an opt-in approach" to obtain parents' informed consent for posttesting use, disposal, and access of their children's blood. *See id.* at PageID.4153; *accord* Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 MINN. J.L. SCI. & TECH. 729, 745 (2014) ("Consent has long been absent in [newborn blood screening] . . . ."); 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, 45 (2011) ("Most states do

[1] In the scientific community, this procedure is called a "neonatal heel prick," and the cards are called "Guthrie cards." Tufik Y. Shayeb, *Informed Consent for the Use and Storage of Residual Dried Blood Samples from State-Mandated Newborn Genetic Screening Programs*, 64 BUFF. L. REV. 1017, 1020 & n.16 (2016).

[2] "The Association of Public Health Laboratories is funded by the [CDC]." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 520 (D.N.J. 1999).

not inform parents that the health department will retain their child's sample or use it for additional research, and few states obtain consent for research using [newborn blood screening]. As such, parents lack the ability to decline their newborn's participation in research.").

For decades, experts and scholars from medicine to law have criticized state-run NSPs. *See, e.g.*, Albert R. Serrano IV, *Pieces of Me: The Immoral and Unjust Appropriation of Genetic Material*, 16 MICH. ST. U. J. MED. & L. 95, 110–15 (2011) (noting that parents generally "want to be fully informed about the circumstances and at least given the option to decline"); Jaclyn S. D'Arminio, Note, *"The Life of the Flesh Is in the Blood": State Storage and Usage of Baby's Blood Sample*, 18 CARDOZO J.L. & GENDER 753, 760 (2012) ("[I]ssues arise when the state's interest in identifying the disease becomes obsolete, and research becomes the state's primary interest." (footnote omitted)); *see also* Alexander Morgan Capron, *Which Ills to Bear?: Reevaluating the "Threat" of Modern Genetics*, 39 EMORY L.J. 665, 684–85 (1990) (discussing "[t]he past lack of attention" to "the ethical and legal issues in genetic screening").

The preeminent concern about state-run NSPs is the lack of "consensus about or commitment to" obtaining parents' informed consent. *See* Ellen Wright Clayton, *Screening and Treatment of Newborns*, 29 HOUS. L. REV. 85, 118 (1992).

Here, too—without obtaining informed consent—Michigan indefinitely stores babies' blood to conduct "medical" and "health" research, to identify victims and suspects of crimes, and to make a substantial profit by selling it to private entities. *See* ECF Nos. 135-12 at PageID.2180–85; 148 at PageID.4847. *See generally Kanuszewski v. MDHHS*, 927 F.3d 396 (6th Cir. 2019).

Considering the 6,000-ish newborns that would not have otherwise been diagnosed with rare blood disorders, it is well understood that enjoining Michigan's unconstitutional conduct would have significant consequences. That said, this case is limited to the claims of only nine

Michiganders. *See Sharpe v. Cureton*, 319 F.3d 259, 273 (6th Cir. 2003) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." (citations omitted)).

B.

On February 8, 2018, Plaintiffs Shannon LaPorte,[3] Adam and Ashley Kanuszewski, and Lynette Wiegand, individually and as parent-guardians of their minor children, sued the MDHHS, Nick Lyon (the then-Director of the MDHHS), Dr. Sandip Shah (the Director of the Bureau of Laboratories), Dr. Sarah Lyon-Callo (an MDHHS epidemiologist), Mary Kleyn (the Manager of the Newborn Screening Section), the Michigan Neonatal Biobank, and Dr. Antonio Yancey (the Director of the Biobank). ECF No. 3.

Plaintiffs' Complaint alleges Defendants violated Plaintiffs' Fourteenth Amendment (substantive due process) rights by extracting blood from their babies then storing and using the blood spots without their constitutionally adequate consent (Counts I and II). ECF No. 26 at PageID.322–25. Plaintiffs also allege Defendants violated their Fourth Amendment rights (against unreasonable searches and seizures) by extracting the blood (Count III) and by indefinitely storing the blood spots (Count IV). *See id.* at PageID.325–29.[4]

[3] On April 4, 2020, this case was consolidated with *LaPorte v. Gordon*, No. 1:20-CV-10089 (E.D. Mich. Apr. 29, 2020). *See* ECF No. 104. But the *LaPorte* Plaintiffs have since voluntarily dismissed their claims from that case. *See* ECF Nos. 114; 116; 118; 120.

[4] *See generally* Laura Beth Cohen, Note, *Informing Consent: Medical Malpractice and the Criminalization of Pregnancy*, 116 MICH. L. REV. 1297, 1304 (2018) (discussing the implications of informed consent for medical procedures in the context of the Fourth Amendment and Fourteenth Amendment); Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking* Daubert, 104 MICH. L. REV. 257, 270 (2005) ("The right of a patient to informed consent has been a staple of U.S. medical malpractice law for [nearly five] decades.").

Defendants filed separate motions to dismiss. ECF Nos. 32, 33, 34. Those motions were granted, and the complaint was dismissed. *See generally Kanuszewski v. MDHHS*, 333 F. Supp. 3d 716 (E.D. Mich. 2018).

C.

On appeal, the Sixth Circuit affirmed and reversed in part, remanding Count II and Count IV for discovery and further proceedings. *See generally Kanuszewski v. MDHHS*, 927 F.3d 396 (6th Cir. 2019). As to the Fourth Amendment (Count IV), the Sixth Circuit held that "the ongoing retention, storage, or use of the [DBS] constitutes a separate, independent violation." *Id.* at 424. This distinction exists, Judge Clay added, despite the possible constitutionality of the initial "drawing and screening." *Id.* To that end, he remanded the question of "whether Plaintiffs consented to any aspect of Defendants' retention, storage, or future use of the blood samples." *Id.* at 425.

Addressing the Fourteenth Amendment (Count II), the Sixth Circuit held that Plaintiff-parents "have a fundamental right to direct the medical care of their children," subject to strict scrutiny. *Id.* at 421. To that end, Judge Clay reasoned that parents' rights (1) "to direct the education and upbringing of [their] children" and (2) "to make decisions concerning the care, custody, and control of [their] children," would both (3) "seem to naturally include the right to direct their children's medical care," because (4) "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment," and (5) "[c]hildren are assumed to be subject to the control of their parents." *Id.* at 418–19 (citations and internal quotation marks omitted).

The Sixth Circuit went on to conclude that Plaintiff-parents plausibly alleged Fourteenth Amendment violations based on the lack of informed consent for the "subsequent retention,

transfer, [] storage," "research," and "selling" of their children's DBS. *Id.* at 420–21. On remand, this Court was directed to answer (1) "whether the evidence demonstrates that Defendants' actions interfered with the parents' right to direct their children's medical care" and (2) "whether those [interfering] actions survive strict scrutiny." *Id.*

But the Sixth Circuit did not address the Nation's history or tradition of parents' right to direct their children's medical care or how that right is implicit in the concept of ordered liberty. *Id.* at 418 (holding that the Constitution "would seem to naturally include [parents'] right to direct their children's medical care"); *see also Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2242 (2022) (holding that any Fourteenth Amendment right "not mentioned in the Constitution[] . . . must be 'deeply rooted in this Nation's history and tradition' and 'implicit in the concept of ordered liberty'" (quoting *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997))). The same is true even though earlier in the same opinion the Sixth Circuit held not only that "parents' substantive due process right to direct the upbringing and education of children . . . . *does not* address the issue of parents' right to control their children's medical care," but also that "parents' right to control their children's medical care" is not clearly established. *Id.* at 415–16 (emphasis added) (citing *Hearring v. Sliwowski*, 712 F.3d 275, 282 (6th Cir. 2013)).

That right exists within a split among the circuits. *Compare Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1203–04 (10th Cir. 2003) (finding a viable "Fourteenth Amendment claim regarding [parents'] right to direct and control the medical treatment of their children" by refusing informed consent), *with Goe v. Zucker*, 43 F.4th 19, 32 n.14 (2d Cir. 2022) (rejecting "Plaintiffs' liberty interest in parenting and liberty interest in informed consent" because "[t]he choice to vaccinate a child remains with the parent and her treating physician"), *and Jenn-Ching Luo v. Owen J. Roberts Sch. Dist.*, 737 F. App'x 111, 116 (3d Cir. 2018) (per curiam) (unpublished) (holding that parents

have no fundamental interest in informed consent of the methodology doctors use in adaptive-behavior assessments of children).

Yet the Sixth Circuit's order requires this Court to apply strict scrutiny to any of Defendants' conduct that lacked informed consent under Michigan law. *Cochran v. Trans-Gen. Life Ins.*, 60 F.Supp.2d 693, 698 (E.D. Mich. 1999) (holding that district courts are bound by the decisions of the Sixth Circuit Court of Appeals); *see also United States v. Montgomery*, No. 1:04-CR-20046-6, 2021 WL 4704832, at *10 (E.D. Mich. Oct. 8, 2021) ("In the absence of Supreme Court precedent directly on point, a district court should decline to 'underrule' established circuit court precedent." (quoting *Hall v. Eichenlaub*, 559 F. Supp. 2d 777, 782 (E.D. Mich. 2008))).

D.

On remand, the parties filed cross-motions for summary judgment. *See* Pls.' Mot. Summ. J., ECF No. 135; Defs.' Mot. Summ. J., ECF No. 147; Def.'s Mot. Summ. J., ECF No. 149. This Court resolved all three summary-judgment motions. *See generally Kanuszewski v. Shah*, 551 F. Supp. 3d 747 (E.D. Mich. 2021).[5]

i.

As required, this Court applied strict scrutiny to Plaintiff-parents' Fourteenth Amendment claims. First, this Court addressed Plaintiff-parents' Fourteenth Amendment claim regarding whether they gave constitutionally sufficient consent to store their children's DBSs (Count II), which involved three issues: whether Plaintiff-parents consented to (1) medical research of their children's DBS, (2) storage of the DBS for research purposes, and (3) storage of the DBS for the

[5] Defendants later filed a motion to exclude expert testimony, ECF No. 143, which was denied, *see generally Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 327710 (E.D. Mich. Feb. 3, 2022).

parents' later use. The parties stipulated to dismiss the latter issue through a partial consent judgment. ECF No. 209.

The Fourteenth Amendment research-consent claims were resolved as a matter of law in favor of DWL and MTL, but they were denied as a matter of law with respect to all the other children because their parents either gave constitutionally adequate consent or denied consent. *See Kanuszewski v. Shah*, 551 F. Supp. 3d at 768. The Fourteenth Amendment research-consent claims were dismissed "as to Kanuszewski children RFK and CKK and Wiegand children LRW, CJW, and HJW because consent for DBS research was obtained." *Id.* at 762. The same claims were dismissed "as to LaPorte child EMO and Wiegand child MLW because the parents declined authorization for research and ha[d] presented no evidence that any research was conducted with the DBS extracted." *Id.* But the Fourteenth Amendment research-consent claims of "DWL (Ashley Kanuszewski's child) and MTL (LaPorte's child)" were evaluated under strict scrutiny because "express consent was not obtained," *id.* at 763, and Plaintiffs did not waive informed consent, *id.* at 765. Under strict scrutiny, Defendants' research "to expand and strengthen the newborn screening program" was narrowly tailored to advance a compelling interest. *Id.* at 766–67. But Defendants' "general public health research" was neither compelling nor narrowly tailored. *See id.* at 767–68.

As to Plaintiffs' consent to storage for purposes of DBS research, this Court dismissed the claims of only "RFK and CKK (Kanuszewski) and LRW, CJW, and HJW (Wiegand)," because their parents "implicitly consented to the storage of[] the research-eligible samples" by "giving consent to conduct research on the DBS." *Id.* at 765. The remaining storage-consent claims were retained as triable. *Id.* at 770 (holding that, though Defendants had a "compelling governmental interest in operating the newborn screening program," there was a genuine question of fact

regarding whether storing the DBS cards of "more than four million people" was "a narrowly tailored process").

ii.

Then this Court addressed Plaintiff-children's Fourth Amendment claims regarding the storage of the blood samples (Count IV). This claim involved two theories: (1) that Defendants' retention of Plaintiff-children's "deeply-private medical and genetic information/data in the State's files and databases" was unreasonable; and (2) that postscreening retention of the DBS cards for "for further use by the State and/or for sale to third-party researchers" was unreasonable. *Id.* at 771–73.

As to the Fourth Amendment data-retention claims, though Defendants demonstrated "a necessity of saving data for an extended period," Plaintiffs "demonstrated that the current 22-year retention policy . . . [might] be unreasonable." *Id.* at 772–73. Thus, the Fourth Amendment data-retention claims were retained as triable issues.

This Court dismissed the Fourth Amendment DBS-retention claims of RFK, CKK, LRW, CJW, and HJW because their parents "consented to research and, implicitly, storage." *Id.* at 774. But the Fourth Amendment DBS-retention claims of EMO, MLW, DWL, and MTL were retained as triable issues because "there was no consent for the storage" of their DBS. *Id.*

II.

The parties have since filed cross-motions for reconsideration that collectively implicate all the issues that this Court addressed when resolving the parties' cross-motions for summary judgment. *See* ECF Nos. 171; 172; 174; *see also* discussion *supra* Section I.D. Both motions have been fully briefed. *See* ECF Nos. 175–81.

Plaintiffs' Motion requests that this Court vacate its dismissal of the Fourteenth Amendment research-consent claims of RFK, CKK, LRW, CJW, and HJW. *See* ECF No. 172 at PageID.5618. In sum, Plaintiffs contend that if this Court would have applied an "informed consent" standard, then genuine questions of fact would remain as to whether Plaintiff-parents' consent was constitutionally adequate. *Id.* at PageID.5625.

If those Fourteenth Amendment research-consent claims are revived, then the respective Fourteenth Amendment storage-consent claims and Fourth Amendment DBS-retention claims would also be revived because they were dismissed based on the inference that consent to research implied consent to storage. *See Kanuszewski v. Shah*, 551 F. Supp. 3d at 765.

Shifting focus, Defendants' Motion asserts this Court should reverse its findings on the Fourteenth Amendment research-consent claims of DWL and MTL because Defendants obtained Plaintiff-parents' general consent under 45 C.F.R. § 46.116(d). ECF No. 174.

The parties thus wrestle with an issue inadvertently addressed in this Court's July 2021 Order. Consent is central not only to whether Defendants interfered with Plaintiff-parents' Fourteenth Amendment right to direct their children's medical care, but also to whether Defendants' retention, storage, or use of the DBS violated Plaintiffs' Fourth Amendment rights. Less than fully addressed was the proposition that the standard for waiving these important rights—informed consent—required more than general consent. A great divide separates general or informational consent.

This Court made an unreasoned assumption that the proper standard for obtaining and waiving consent comes from 45 C.F.R. § 46.116, as cited in the NSP. *See Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 755–65 (E.D. Mich. 2021). The correct standard, however, is Michigan law's informed-consent standards.

To right that wrong, this Court will explain why the applicable law requires Michigan's informed-consent standard in this case and then apply that standard to the parties' summary-judgment motions. *See Dorchy v. Fifth Third Bank*, No. 1:21-CV-10078, 2022 WL 987177, at *3 (E.D. Mich. Mar. 31, 2022) ("This Court may clarify an order *sua sponte* to 'correct a mistake arising from oversight or omission whenever one is found in a judgment order, or other part of the record.'" (quoting FED. R. CIV. P. 60(a))).

A.

Contrary to this Court's prior analysis, Michigan's NSP is not subject to 45 C.F.R. § 46.116. As the Third Circuit has interpreted it, § 46.101(b)(5)(i) "specifically excludes from [§ 46] research and demonstration projects designed for 'public benefit or service programs.'" *C.K. v. N.J. Dep't of Health & Hum. Servs.*, 92 F.3d 171, 189 (3d Cir. 1996). As Defendants and the APHL have repeatedly explained, the NSP is a public-benefit program. *See* discussion *supra* Section I.A.

According to its plain text, § 46 applies to federal research and "does not affect any state or local laws or regulations . . . that may otherwise be applicable and that provide additional protections for human subjects." 45 C.F.R. § 46.101(a), (f); *accord* 45 C.F.R. § 46.116(i) ("The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws . . . that require additional information to be disclosed in order for informed consent to be legally effective."); *cf. Mack v. Ventracor, Ltd.*, No. CIV.A. 10-CV-02142, 2011 WL 890795, at *12 (E.D. Pa. Mar. 9, 2011) (holding that the same preemption provision from another regulation applies to § 46.116(e), which governs waivers of consent in state-approved programs). That is, § 46's IRB-waiver provision only applies to state programs that do not have additional consent protections.

Michigan law provides such additional protections. Michigan's NSP statute requires the State (1) to obtain informed consent for all conduct other than drawing and screening DBS for an enumerated list of disorders, (2) to develop a storage and disposal schedule for tested DBS, and (3) to make an offer if it wants an additional DBS.[6] *See generally* MICH. COMP. LAWS § 333.5431. And, in contrast to 45 C.F.R. § 46.116, Michigan's applicable informed-consent statutes do not permit Internal Review Boards (IRB) to waive informed consent. *Compare* MICH. COMP. LAWS § 333.17020 (omitting discussion of IRB waiver), *and* MICH. COMP. LAWS § 333.17520 (same), *with* 45 C.F.R. § 46.116(e)(1) (permitting an IRB to waive informed consent). Although Michigan's NSP statute refers to 45 C.F.R. § 46, it does so with respect to only the "manner" in which "the medical research is conducted." MICH. COMP. LAWS § 333.5431(7)(b).

Thus, Michigan law does not apply § 46.116's standards of obtaining or waiving consent. *See also* discussion *infra* Section II.B. Instead, Michigan's NSP explicitly retains informed consent for everything other than the initial testing. MICH. COMP. LAWS § 333.5431(2).

B.

Michigan's informed-consent statutes require "the written, informed consent" of "the test subject or the legally authorized representative of the test subject." MICH. COMP. LAWS §§ 333.17020, 333.17520.

Michigan's NSP waives the informed-consent requirement in only one circumstance: testing for an exclusive list of seven conditions plus "[o]ther treatable but otherwise disabling conditions as designated by the department." *See* MICH. COMP. LAWS § 333.5431(1), (2). Such

[6] Notably, state courts, not federal courts, are the final arbiters of state laws and constitutions. *Danforth v. Minnesota*, 552 U.S. 264, 291 (2008) (Roberts, C.J., dissenting); *accord White v. Steele*, 602 F.3d 707, 711 (6th Cir. 2009) (citing *Thompson v. Bock*, 215 F. App'x 431, 436 (6th Cir. 2007) (unpublished)).

testing must "be administered and reported within a time and under conditions prescribed by the department." MICH. COMP. LAWS § 333.5431(2).

Michigan law therefore requires informed consent for all DBS-related conduct except the initial testing—including storage, transfer, sale, research, and any other use of all DBS, as well as drawing an additional DBS.

For tested DBS, Michigan law requires the State to "develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed." MICH. COMP. LAWS § 333.5431(7)(a). During that retention period, the State must "[a]llow the blood specimens to be used for medical research . . . in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under [45 C.F.R. §§ 46.101–124 (2009)]." MICH. COMP. LAWS § 333.5431(7)(b).

Michigan law, for reasons that are unclear, does not waive informed consent for the required retention, disposal, or medical research of tested DBS. *See* MICH. COMP. LAWS § 333.5431(2) (waiving informed consent for the "tests" and nothing else). In other words—though Michigan law requires the State to draw, to test, and to establish a storage timeframe (during which medical research is permitted) between testing and disposal—the State must receive informed consent under § 333.17020 and § 333.17520 for posttesting storage, disposal, and medical research of any tested DBS. Thus, if the State does not obtain informed consent, then it must dispose of any tested DBS after testing is complete.

Michigan law also permits the healthcare professional or facility to make "an offer" for "an additional" DBS "to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of [testing]." MICH. COMP. LAWS § 333.5431(9). In this way, the State may draw one additional DBS if and only if the parents "accept" a separate "offer" for it.

The State may only use the additional DBS "for future identification purposes" and nothing else. *See* MICH. COMP. LAWS § 333.5431(9).

But all conduct involving the additional DBS also requires informed consent. *See* MICH. COMP. LAWS § 333.5431(2) (waiving informed consent for the "tests" and nothing else). In this way, the State must obtain informed consent to draw, to store "in a safe place," and to use the additional DBS "for future identification purposes." MICH. COMP. LAWS § 333.5431(9). If informed consent is obtained, then the State must "preserve" the additional DBS "in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination." MICH. COMP. LAWS § 333.5431(9). That said, there is no apparent time limit on how long the State may store the additional DBS so long as it obtains informed consent for that timeframe. *See* MICH. COMP. LAWS § 333.5431(9).

C.

As indicated, Michigan's informed-consent laws govern the issue of whether Defendants received or exceeded the scope of Plaintiff-parents' informed consent. *See Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 279–81 (1990) (holding that the United States Constitution permits states to implement stricter informed-consent standards, which create constitutionally protected liberty interests); *id.* at 292 (O'Connor, J., concurring) ("[T]he more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the 'laboratory' of the States in the first instance." (internal citation omitted)); *Doe v. District of Columbia*, 206 F. Supp. 3d 583, 618–23 (D.D.C. 2016) (holding that the District of Columbia's informed-consent statute created a constitutionally protected liberty interest under the Due Process Clause).

Michigan's "doctrine of informed consent requires a physician to warn a patient of the risks and consequences of a medical procedure." *Wlosinski v. Cohn*, 713 N.W.2d 16 (Mich. Ct. App. 2005). To that end, the "doctor must engage in a substantive discussion with the parent of a minor patient in order to share these risks and consequences and to obtain the parent's consent for the proposed medical procedure." *Lucas v. Awaad*, 830 N.W.2d 141, 150-51 (Mich. Ct. App. 2013).

"Many clinicians equate informed consent with obtaining a signature on a consent form, which, of course, is usually documentation of the informed consent process that has preceded execution, and does not necessarily mean that the elements of informed consent have been accomplished at all." Kathleen M. Boozang, *Fundamentals of Provider Liability*, American Health Lawyers Association Seminar at the Palmer House Hilton in Chicago, IL (Nov. 8, 2006), AHLA-PAPERS P11080603, at *4 (WL).

But a signed informed-consent form is not dispositive. *Cistrunk v. Oakwood Heritage Hosp.*, No. 287457, 2010 WL 2384887, at *4 (Mich. Ct. App. June 15, 2010) (per curiam) (unpublished) (holding that, with respect to the adequacy a signed informed-consent form, "competing evidence on both sides . . . create[s] an issue of fact for the jury"); *cf. Baker v. Beird*, No. 341707, 2019 WL 1211465, at *3 (Mich. Ct. App. Mar. 14, 2019) (per curiam) (unpublished) (holding that an informed-consent form is not a binding contract).

For example, despite a signed informed-consent form, informed consent is a triable issue of fact if plaintiffs testify that they did not give informed consent, s*ee, e.g.*, *Rogalski v. Smith*, No. 350120, 2020 WL 6111598, at *6 (Mich. Ct. App. Oct. 15, 2020) (per curiam) (unpublished), or that they did not sign the informed-consent form, *see, e.g.*, *Cornelius v. Joseph*, No. 237956, 2003 WL 462378, at *3 (Mich. Ct. App. Feb. 21, 2003) (per curiam) (unpublished). Similarly, informed consent is a triable issue if there is conflicting expert testimony about "the standard of care for

informed consent." *Halverson v. Garrett*, No. 223206, 2001 WL 716966, at *2 (Mich. Ct. App. Mar. 13, 2001) (per curiam) (unpublished); *see also Cornelius v. Joseph*, 688 N.W.2d 279, 279 (Mich. 2004) (Markman, J., dissenting) (stating expert testimony may establish whether "an informed consent form purportedly signed by plaintiff" is "sufficient to obtain informed consent"). Indeed, a signed informed-consent form does not establish the proper standard of care, which is for the jury to decide. *See Juckett v. Elluru*, No. 260350, 2006 WL 2924664, at *4 (Mich. Ct. App. Oct. 12, 2006) (per curiam) (unpublished).

"The burden of establishing that a defendant has breached the applicable standard of care is on the plaintiff." *Cistrunk v. Oakwood Heritage Hosp.*, No. 287457, 2010 WL 2384887, at *4 (Mich. Ct. App. June 15, 2010) (citing *Wiley v. Henry Ford Cottage Hosp.*, 668 N.W.2d 402, 407 (Mich. Ct. App. 2003)). And it is well established that courts must "'indulge every reasonable presumption against waiver' of fundamental constitutional rights and . . . 'not presume acquiescence in the loss of fundamental rights.'" *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938) (citations omitted); *accord People v. Russell*, 684 N.W.2d 745, 749 & n.10 (Mich. 2004) ("[I]t is a long-held principle that courts are to make every reasonable presumption against the waiver of a fundamental constitutional right.").

Accordingly, with respect to all conduct other than the initial blood screen, Defendants must have obtained Plaintiff-parents' "written, informed consent . . . that confirms . . . at a minimum" that Defendants "explained, and [that] the test subject or the legally authorized representative of the test subject understands":

> (a) The nature and purpose of the presymptomatic or predictive genetic test.
> (b) The effectiveness and limitations of the presymptomatic or predictive genetic test.
> (c) The implications of taking the presymptomatic or predictive genetic test, including, but not limited to, the medical risks and benefits.

> (d) The future uses of the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test.
> (e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the test subject.
> (f) Who will have access to the sample taken from the test subject in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test, and the test subject's right to confidential treatment of the sample and the information.

MICH. COMP. LAWS §§ 333.17020, 333.17520; *see* MICH. COMP. LAWS § 333.5431(2); *accord* Nathan Rice, Commentary, *My Kid, the Future Olympian: Predictive and Genetic Aptitude Testing and the Case for Regulation*, 34 J. LEGAL MED. 117, 128 (2013) (noting that § 333.17520 requires that the patient is "informed about a number of different subjects, including the test's nature and purpose, the test's limitations and effectiveness, the test's risks and benefits, the future use of the sample, the meaning of the test's results, and who will have access to the test's information."); Sarah Fendrick, Note, *The Role of Privacy Law in Genetic Research*, 4 I/S: J.L. & POL'Y FOR INFO. SOC'Y 803, 813 (2009) (noting that § 333.17520 "require[s] that informed consent incorporate a statement of future use of the sample and specify who will have access to the sample."). Plaintiff-parents might also have a right not to know the DBS test results. *See* Emily Scholtes, Note, *Incorporating Cost into the Return of Incidental Findings Calculus: Defining a Responsible Default for Genetics and Genomics Researchers*, 100 MINN. L. REV. 1171, 1190 (2016) ("Related to the issues of consent and reconsent, many ethicists argue that a person has a right not to know one's own genes or genomic sequence . . . .").

The duty to obtain informed consent belongs to "the physician or the individual acting under the delegatory authority of the physician." MICH. COMP. LAWS §§ 333.17020(2), 333.1750(2). In practice, however, though "[t]he physician is the best person to properly discuss the particular procedure with the patient," the duty to obtain informed consent falls on the

healthcare professional who signs the informed-consent form, even if the hospital supplies the form to the parent. *Lincoln v. Gupta*, 370 N.W.2d 312, 318 (Mich. Ct. App. 1985). If no such signature is present, then the duty belongs to the "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." MICH. COMP. LAWS § 333.5431.

D.

Defendants' conduct in effectuating the NSP may not violate the Due Process Clause of the United States Constitution.

As Judge Clay explained, Plaintiff-parents have a "fundamental liberty interest" in giving "informed consent to Defendants' actions." *Kanuszewski v. MDHHS*, 927 F.3d 396, 420 (6th Cir. 2019). Accordingly, Plaintiff-parents have a constitutionally protected right to refuse informed consent for their children's medical care. *See id.* at 418 ("Parents possess a fundamental right to make decisions concerning the medical care of their children."); *id.* ("[A] competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." (quoting *Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990))); *see also Cruzan*, 497 U.S. at 277 ("[T]he common-law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment."); *In re Rosebush*, 491 N.W.2d 633, 635 (Mich. Ct. App. 1992) ("The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, the right to refuse medical treatment and procedures." (citing *Werth v. Taylor*, 475 N.W.2d 426, 428 (Mich. Ct. App. 1991))).

In this way, for any tested DBS, Defendants violated Plaintiff-parents' fundamental rights if they lacked or exceeded the scope of Plaintiff-parents' informed consent for posttesting storage, transfer, research, sale, discard, or use.

Similarly, as to any additional DBS, if Defendants did not receive or exceeded the scope of Plaintiff-parents' informed consent for the drawing, storing "in a safe place," use for "future identification purposes," or any other conduct not permitted by Michigan law (e.g., test, transfer, research, sale, use), then Defendants violated Plaintiff-parents' fundamental rights.

Simply put—under the Sixth Circuit's opinion remanding the case—if Defendants did not comply with Michigan's informed-consent statutes for any conduct other than the initial testing of the DBS, then they violated Plaintiff-parents' substantive-due-process rights to direct the medical care of their children.

III.

A.

A motion for summary judgment should be granted only 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(a). The movant has the initial burden of "identifying those portions of [the record that] it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmovant, who must set out specific facts showing "a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (citation omitted). The nonmovant must demonstrate more than "some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Indeed, the "mere existence of a scintilla of evidence" does not establish a genuine issue of material fact. *Liberty Lobby*, 477 U.S. at 252.

The court must review the evidence and draw all reasonable inferences in favor of the nonmovant to determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251–52; *see Lossia v. Flagstar Bancorp, Inc.*, 895 F.3d 423, 428 (6th Cir. 2018).

Summary judgment will be granted if the nonmovant "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.*, 477 U.S. at 322. But summary judgment will be denied "[i]f there are . . . 'genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.'" *Hancock v. Dodson*, 958 F.2d 1367, 1374 (6th Cir. 1992) (citation omitted).

B.

Fundamental Liberty Interests of LaPorte (EMO) and Wiegand (MLW).

The informed-consent forms for EMO and MLW[7] demonstrate their parents' informed consent to defer discarding their DBS until further notice. *See* ECF No. 147-17 at PageID.4311. The form states, "You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening." *Id.* No reasonable juror could find that this statement did not inform EMO's and MLW's parents that not contacting MDHHS permitted continued storage of their children's DBS. Accordingly, the disposal-consent claims of EMO and MLW will be dismissed.

But Michigan law requires that the signed writing "confirms" not only that the parents "understand" to what they are consenting but also that the consented conduct has been "explained" to the parents. MICH. COMP. LAWS §§ 333.17020(2), 333.17520(2).

[7] The informed-consent forms of EMO and MLW are identical. *Compare* ECF No. 147-17 at PageID.4311 (EMO), *with* ECF No. 147-21 at PageID.4319 (MLW).

With respect to the tested DBS, though the informed-consent forms vaguely state that the DBS "may still be used by the state lab to ensure that newborn screening detects those at risk," they did not provide the parents with the option to refuse storage, transfer, sale, use for future identification purposes, use to maintain and to expand the NSP, or any other use by private parties or the State. *See* ECF No. 147-17 at PageID.4311.

The same is true with respect to the one additional DBS that Michigan law permits Defendants to draw for future identification purposes with parental permission. *See id.* Moreover, the informed-consent form does not, as Michigan law requires, *see* MICH. COMP. LAWS § 333.5431(9), make "an offer to draw [the one] additional blood specimen," *see* ECF No. 147-17 at PageID.4311.

Regarding storage, the forms only indicate that "[b]lood spots will be stored forever." *Id.* Thus, there is no way to "confirm" Plaintiff-parents' "understanding" of their informed consent. *See* MICH. COMP. LAWS §§ 333.17020, 333.17520. For example, the record does not demonstrate that they were informed of the quantity of both tested and identification DBS that Defendants would store. *Cf.* MICH. COMP. LAWS § 440.2201 ("[T]he contract is not enforceable under this subsection beyond the quantity of goods shown in the writing."); *Lorenz Supply Co. v. Am. Standard, Inc.*, 358 N.W.2d 845, 847 (Mich. 1984) ("The quantity term must, however, under § 2-201, be specifically stated."). The same is true of the purpose, location, and quality of storage. *See, e.g.*, MICH. COMP. LAWS § 333.5431(9) (requiring the identification DBS to "be preserved in a manner that does not require special storage conditions or techniques"). Indeed, contrary to Michigan law, the forms state neither that the identification DBS "should be kept in a safe place" nor that they might be stored by a private party rather than the State. Drawing all reasonable inferences in Defendants' favor as this Court must, no reasonable person could conclude beyond

a preponderance of the evidence that those forms confirm Plaintiff-parents' understanding of the nature and quality of their informed consent to storage.

The record demonstrates that private researchers pay the State and the Biobank for DBS. *See* ECF No. 145-4 at PageID.3965–66 ("That is something that the State does. They charge, and then we charge also."). There is no way to "confirm" Plaintiffs' "understanding" that their children's DBS would be sold to a third-party researcher without that being on the informed-consent form. Indeed, the forms state explicitly that the DBS will be "used by the state lab." *See* ECF No. 147-17 at PageID.4311. In other words, there is no evidence of Plaintiff-parents' informed consent to sell the DBS.

The record also demonstrates that the State used the DBS for crime-victim identification. *See* ECF No. 145-3 at PageID.3938 ("[T]here is a legal process that they would have to go through."). The potential for crime-victim identification is not disclosed on the informed-consent form. *See* ECF No. 147-17 at PageID.4311.

And the record demonstrates that, even if parents refuse to consent to medical research, Defendants not only store the children's DBS "forever" but also use it "in maintaining and expanding the newborn screening program, allowing for the identification and treatment of congenital disorders in all newborns." ECF No. 147 at PageID.4219; *see also* ECF No. 147-17 at PageID.4311. Defendants also use these "[r]esidual DBS specimens" for other public-health research, "quality improvement[,] and test development." ECF Nos. 146 at PageID.4158; 147 at PageID.4223–24. Drawing all reasonable inferences in Defendants' favor, they conduct research even when consent for medical research is refused.

As explained, Michigan law does not waive informed consent for any of that conduct. *See* discussion *supra* Section II.B. Further, contrary to the way that Michigan law structures the NSP,

the informed-consent form does not distinguish between the tested DBS and the one additional DBS permitted by Michigan law. *See* ECF No. 147-17 at PageID.4311 ("Your choice applies to all blood spots collected for newborn screening.").

Defendants' only potential argument to the contrary is that the informed-consent forms requested that Plaintiff-parents "please read" the "Your Baby's Blood Spots" pamphlet. *See id.*

But no reasonable person could conclude that a mere request for informed consent proves that it was given. *See* MICH. COMP. LAWS § 333.5431 (requiring that the parent "accepts the offer of an additional blood specimen"). If, by contrast, the informed-consent form had a checkbox for parents to confirm that they understood the contents of the pamphlet, then the form's reference to pamphlet might lend a triable issue.[8] But that is not the case.

For these reasons, drawing all reasonable inferences in Defendants' favor, they did not obtain informed consent from Plaintiff-parents of EMO or MLW for the following conduct:

(1) research of the tested DBS;
(2) storage of tested DBS;
(3) transfer of tested DBS;
(4) sale of tested DBS;
(5) use of tested DBS to maintain and to expand the NSP;
(6) use of tested DBS for any other purpose by the State;
(7) use of tested DBS for any other purpose by private parties;
(8) draw of identification DBS;
(9) research of identification DBS;
(10) storage of identification DBS;
(11) transfer of identification DBS;
(12) sale of identification DBS;
(13) use of identification DBS for future identification purposes;
(14) use of identification DBS to maintain and to expand the NSP;
(15) use of identification DBS for any other purpose by the State; and
(16) use of identification DBS for any other purpose by private parties.

[8] The same might be true with respect to the "After Newborn Screening" booklet referenced in other informed-consent forms.

Accordingly, Plaintiff-parents of EMO and MLW have 16 Fourteenth Amendment substantive-due-process claims that will be analyzed under and fail strict scrutiny. *See Kanuszewski v. MDHHS*, 927 F.3d 396, 420–21 (6th Cir. 2019); discussion *infra* Section III.E.

C.

Fundamental Liberty Interests of Kanuszewski (DWL) and LaPorte (MTL).

As to DWL and MTL, Defendants violated their parents' substantive-due-process rights. Defendants request that this Court reconsider that finding because, in their view, there is a genuine question of fact as to whether they complied with 45 C.F.R. § 46.116(d) by having an Institutional Review Board waive consent on behalf of DWL's and MTL's parents. *See generally* ECF No. 174. But the IRB waiver cannot establish informed consent as a matter of law because, as explained earlier, Michigan law did not waive informed consent and Defendants did not even attempt to seek informed consent from Plaintiff-parents of DWL or MTL. Even if § 46 was apt, the provision that Defendants cite provides a standard for general consent—not informed consent as Michigan law required—and is therefore constitutionally inadequate here. With respect to the NSP, Michigan has not adopted federal consent standards or waived the common-law requirement of informed consent. *See* MICH. COMP. LAWS § 333.5431(2), 7(B); *see also* discussion *supra* Sections II.A, II.B, II.C.

For these reasons, drawing all reasonable inferences in Defendants' favor, they did not obtain informed consent from Plaintiff-parents of DWL or MTL for the following conduct:

(1) research of the tested DBS;
(2) storage of tested DBS;
(3) transfer of tested DBS;
(4) sale of tested DBS;
(5) use of tested DBS to maintain and to expand the NSP;
(6) use of tested DBS for any other purpose by the State;
(7) use of tested DBS for any other purpose by private parties;
(8) disposal of tested DBS;

(9) draw of identification DBS;
(10) research of identification DBS;
(11) storage of identification DBS;
(12) transfer of identification DBS;
(13) sale of identification DBS;
(14) use of identification DBS for future identification purposes;
(15) use of identification DBS to maintain and to expand the NSP;
(16) use of identification DBS for any other purpose by the State;
(17) use of identification DBS for any other purpose by private parties; and
(18) disposal of identification DBS.

Accordingly, Plaintiff-parents of DWL and MTL have 18 Fourteenth Amendment substantive-due-process claims that will be analyzed under and fail strict scrutiny. *See Kanuszewski v. MDHHS*, 927 F.3d at 420–21; discussion *infra* Section III.E.

D.

Fundamental Liberty Interests of Kanuszewski (RFK, CKK) and Wiegand (LRW, CJW, HJW).

For the same reasons discussed with respect to EMO and MLW, drawing all reasonable inferences in Defendants' favor, they did not obtain informed consent from Plaintiff-parents of RFK, CKK, LRW, CJW, or HJW for the following conduct:

(1) storage of tested DBS;
(2) transfer of tested DBS;
(3) sale of tested DBS;
(4) use of tested DBS to maintain and to expand the NSP;
(5) use of tested DBS for any other purpose by the State;
(6) use of tested DBS for any other purpose by private parties;
(7) disposal of tested DBS;
(8) draw of identification DBS;
(9) storage of identification DBS;
(10) transfer of identification DBS;
(11) sale of identification DBS;
(12) use of identification DBS for future identification purposes;
(13) use of identification DBS to maintain and to expand the NSP;
(14) use of identification DBS for any other purpose by the State;
(15) use of identification DBS for any other purpose by private parties; and
(16) disposal of identification DBS.

See discussion *supra* Section III.B. The only difference is that the informed-consent forms of RFK, CJW, and LRW do not even allude to storage. *See, e.g.*, ECF No. 147-15 at PageID.4307. Accordingly, Plaintiff-parents of RFK, CKK, LRW, CJW, or HJW have 16 Fourteenth Amendment substantive-due-process claims that will be analyzed under and fail strict scrutiny. *See Kanuszewski v. MDHHS*, 927 F.3d at 420–21; discussion *infra* Section III.E.

The only possible conduct for which these Plaintiff-parents *might* have given their informed consent is for research, because that is the only subject included on their informed-consent forms.[9]

But Plaintiffs offer reliable expert testimony not only that Plaintiff-parents' purported consent was constitutionally inadequate, *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 327710, at *3–6 (E.D. Mich. Feb. 3, 2022) (expert testimony of Dr. Elizabeth R. Eisenhauer), but also that Defendants' method for obtaining informed consent is constitutionally inadequate, *id.* (expert testimony of Professor Sonia Mateu Suter).

For this reason alone, there is a triable question of fact with respect to whether Plaintiff-parents gave informed consent to research of DBS belonging to RFK, CKK, LRW, CJW, and HJW. *Halverson v. Garrett*, No. 223206, 2001 WL 716966, at *2 (Mich. Ct. App. Mar. 13, 2001) (per curiam) (unpublished); *see also Cornelius v. Joseph*, 688 N.W.2d 279, 279 (Mich. 2004) (Markman, J., dissenting).

Further, Plaintiff-parents contend they did not give their informed consent. They state their consent was not voluntary because they signed the forms a mere 24 hours after Plaintiff-mothers

[9] The informed-consent forms for RFK, LRW, and CJW are identical. *Compare* ECF No. 147-15 at PageID.4315 (RFK), *and* ECF No. 147-18 at PageID.4313 (LRW), *with* ECF No. 147-19 at PageID.4315 (CJW). The same is true of the forms for CKK and HWJ. *Compare* ECF No. 147-16 at PageID.4309 (CKK), *with* ECF No. 147-20 at PageID.4317 (HJW). The only difference between the two forms is inconsequential to this order. *Compare* ECF No. 147-15 at PageID.4315 ("medical research"), *with* ECF No. 147-16 at PageID.4309 ("health research").

gave birth. ECF No. 135 at PageID.1944–45. They add that Defendants did not explain the meaning of "research," that the DBS are sold, that private companies have access to the DBS, or how the DBS can be used to target certain demographics of babies and to reveal the identity of the respective baby. *Id.* at PageID.1943.

This too creates a triable issue of fact regarding informed consent for research. *See Rogalski v. Smith*, No. 350120, 2020 WL 6111598, at *6 (Mich. Ct. App. Oct. 15, 2020) (per curiam) (unpublished).

Again, the only argument to the contrary is the informed-consent form's reference to "[p]lease read" a booklet. *See, e.g.*, ECF No. 147-15 at PageID.4307. As explained, that argument fails because the forms neither demonstrate whether the parents actually read the booklet nor give the parents the opportunity to confirm their understanding of the booklet's contents. *See* discussion *supra* Section III.B.

For these reasons, there is a triable question of fact as to whether the parents of RFK, CKK, LRW, CJW, and HJW gave their informed consent to research. As explained later, Defendants conduct cannot pass the strict-scrutiny standard required by the Sixth Circuit's analysis. *See* discussion *infra* Section III.E. Therefore, if it is found that there is a lack of informed consent for research, then Defendants are liable under Count II for this conduct.

E.

Strict Scrutiny.

In order to pass strict scrutiny for each of the above-listed informed-consent violations, Defendants must prove that their conduct is the least restrictive way to advance a compelling government interest. *Kennedy v. Bremerton Sch. Dist.*, 142 S. Ct. 2407, 2411 (2022) (citing *Church*

of Lukumi Babalu Aye, Inc. v. Hialeah, 508 U.S. 520, 546 (1993)). First the tested-DBS conduct will be addressed, followed by the identification-DBS conduct. Neither passes strict scrutiny.

Michigan undoubtedly has some level of interest in detecting rare blood diseases in its infant population. *See Wisconsin v. Yoder*, 406 U.S. 205, 220 (1972) (discussing the States' "undoubted power to promote the health, safety, and general welfare" of their populations) (collecting cases); *see also Globe Newspaper Co. v. Superior Ct. for Norfolk Cnty.*, 457 U.S. 596, 607–08 (1982) (acknowledging states' compelling interest in "safeguarding the physical and psychological well-being of a minor").

But, as the Sixth Circuit emphasized, Defendants' posttesting conduct is not necessary to effectuate that interest because "the health of the child is no longer a stake." *Kanuszewski v. MDHHS*, 927 F.3d 396, 421 (6th Cir. 2019). That is, after the DBS is tested, Defendants no longer need to test the DBS.

Defendants' conduct fails strict scrutiny with respect to posttesting research, storage, transfer, sale, discard, and all other use of the tested DBS. Defendants allege they need the posttesting DBS to maintain and to expand the NSP and to conduct medical and public-health research. *See* ECF No. 147 at PageID.4219, 4229. Even if those interest were compelling, Defendants need not store, transfer, sell, research, or do any other posttesting conduct with tested DBS without informed consent; they have spent decades collecting millions of DBS that they could use instead. *See* ECF No. 147-11 at PageID.4282; *see also* ECF No. 147 at PageID.4219 (acknowledging that "all residual DBS may be used by MDHHS for limited purposes necessary to maintain the ongoing function of the [NSP]"). Moreover, Defendants could simply obtain informed consent, which is obviously less restrictive on Plaintiffs' rights than not obtaining their consent. For example, Defendants could simply create a form with separate checkboxes for all the

conduct for which Michigan law does not waive informed consent. *See* discussion *supra* Section III.C; *see also* Hallie P. Gillam, Note, *Forensic Genealogy: The Benefits, the Risks, and the Immediate Need for Legislative Intervention*, 9 BELMONT L. REV. 616, 640 (2022) (arguing that genetic databases ought "to have an 'opt-in' option").

Defendants' conduct also fails strict scrutiny with respect to research, storage, transfer, sale, discard, and all other use of the one identification DBS. There might be a compelling state interest in identifying victims of crimes. *See Donohue v. Hoey*, 109 F. App'x 340, 361 (10th Cir. 2004) (unpublished); *see also People v. James*, 931 N.W.2d 50, 58 (Mich. Ct. App. 2018) (noting Michigan's compelling interest "in discovering previously unreported crimes, as well as subsequently investigating and prosecuting them." (collecting cases)); *cf. State v. March*, 395 S.W.3d 738, 787 (Tenn. Crim. App. 2011) ("[T]he State's interest in *detecting* crime and punishing offenders is compelling . . . ." (emphasis added)). But none of Defendants' conduct is narrowly tailored to that end. Victims of crimes can be identified by dental records, fingerprints, palm prints, skin prints, anthropometry, facial recognition, iris and retina identification, x-rays, CT scans, photographs, documents, circumstantial means (e.g., wedding ring), scars, tattoos, amputations, head fractures, orthopedic hardware, prosthesis, and the identification of a friend, relative, or other person. *Tompkins v. Moore*, 193 F.3d 1327, 1339–40 (11th Cir. 1999) *Vernon v. Hamby*, 767 F.2d 922 (6th Cir. 1985) (Jones, J., dissenting); Wayne A. Logan, *Policing Identity*, 92 B.U. L. REV. 1561, 1567–78 (2012). *See generally* Monique C.M. Leahy, *Autopsies*, 98 AM. JUR. PROOF OF FACTS 3d 87 (2022). With this torrent of techniques available to identify the deceased, Defendants cannot possibly demonstrate that any of its conduct is necessary to identify victims of crimes.

Because none of Defendants' conduct passes strict scrutiny with all reasonable inferences drawn in their favor, Plaintiffs' Motion for Summary Judgment will be granted as to Count II.

F.

In sum, the only remaining questions of fact under Count II are the research-consent claims of Adam and Ashley Kanuszewski (RFK, CKK) and Lynette Wiegand (LRW, CJW, HJW). Summary judgment will be granted for all the other conduct.

IV.

Plaintiff-children's Fourth Amendment claims regarding the storage of the blood samples (Count IV) must also be addressed.

As to the Fourth Amendment data-retention claims of all nine Plaintiff-children, this Court previously held that "[t]here remain questions of fact relevant to whether Defendants' ongoing warrantless retention of the DBS and related data is reasonable." *Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 775 (E.D. Mich. 2021); *see also* discussion *supra* Section I.D.ii. After further review, that holding is still sound.

Accordingly, the Fourth Amendment data-retention claims of DWL, MTL, RFK, CKK, LRW, CJW, HJW, MLW, and EMO will proceed to trial.

Similarly, the Fourth Amendment DBS-retention claims of EMO, MLW, DWL, and MTL were retained as triable issues because "there was no consent for the storage" of their DBS. *Kanuszewski v. Shah*, 551 F. Supp. 3d at 774; *see also* discussion *supra* Section I.D.ii. That holding also remains sound.

Accordingly, the Fourth Amendment data-retention claims of EMO, MLW, DWL, and MTL will proceed to trial.

But this Court dismissed the Fourth Amendment DBS-retention claims of RFK, CKK, LRW, CJW, and HJW because their parents "consented to research and, implicitly, storage." *Kanuszewski v. Shah*, 551 F. Supp. 3d at 774; *see also* discussion *supra* Section I.D.ii.

That holding, however, will be vacated because Defendants violated the Fourteenth Amendment substantive-due-process rights of Plaintiff-parents of RFK, CKK, LRW, CJW, and HJW with respect to storage. *See* discussion *supra* Sections III.D, III.E. (discussing how informed consent to research does not necessarily entail informed consent to storage). Therefore, there is a genuine question of fact regarding the Fourth Amendment DBS-retention claims of RFK, CKK, LRW, CJW, and HJW.

Accordingly, the Fourth Amendment data-retention claims of RFK, CKK, LRW, CJW, and HJW will proceed to trial.

In sum, questions of fact remain regarding all Plaintiffs' claims in Count IV.

V.

Accordingly, it is **ORDERED** that Plaintiff's Motion for Reconsideration, ECF No. 172, is **GRANTED**.

Further, it is **ORDERED** that Defendants' Motion for Reconsideration, ECF No. 174, is **DENIED**.

Further, it is **ORDERED** that the July 2021 Order, ECF No. 171, is **VACATED IN PART**, as demonstrated by the following table:

Claim	Plaintiffs	Status
Tested DBS—research (Count II)	Kanuszewskis (RFK, CKK) Wiegand (LRW, CJW, HJW)	Triable
Identification DBS—research (Count II)	Kanuszewskis (RFK, CKK) Wiegand (LRW, CJW, HJW)	Triable
Data-retention (Count IV)	All	Triable
Tested DBS-retention (Count IV)	All	Triable
Identification DBS-retention (Count IV)	All	Triable
Tested DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—sale (Count II)	All	Summary Judgment for Plaintiffs

Tested DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting State use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting private-party use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—disposal (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—draw (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—sale (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—future identification purposes (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—other State use (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—other private-party use (Count II)	All	Summary Judgment for Plaintiffs
Identification DBS—disposal (Count II)	All	Summary Judgment for Plaintiffs

This is not a final order and does not close the case.

Dated: September 13, 2022

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge