WEBVTT

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AUDIO: Recording in progress.

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SANDRA SOO-JIN LEE: Good morning! Ah,

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afternoon or evening, depending on which part

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of the world you are Zooming into or listening

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to this recording today. I am Sandra Soo-Jin

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Lee, and I'm delighted to welcome you to our

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July ELSI Friday Forum, Legal Challenges to

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Newborn Screening Research. The Forum is

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hosted by the Center for ELSI Resources and

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Analysis and held on the second Friday of every

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month for one hour starting at 12:00 noon

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Eastern time. We also have a Zoom room

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reserved for 30 minutes for more informal

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discussion immediately after the panel? The

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link for that Zoom room will be dropped into

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the chat towards the end of the hour.

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For those of you who might be new to the

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Center for ELSI Resources and Analysis, or

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CERA, we provide resources to support research

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on the ethical, legal, and social implications

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of genetics and genomics, and serve to connect

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scholars, scientists, policymakers, health care

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providers, journalists, members of the public,

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and others to engage ELSI issues. CERA is

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funded by the National Human Genome Research

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Institute at NIH, and is managed by teams at

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Stanford and Columbia Universities, ah, in

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partnership with the Hastings Center and

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Harvard University.

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I encourage you to visit CERA's online

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platform, eLSIhub.org, for the recording and

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transcript of this forum and related

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references.

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Please use the link in the chat to access

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the newel see hub collection, ethical issues

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related to research uses of residual dried

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Residual Dried

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Bloodspots from Newborn Screening. This has

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been curated by Julia Cakici, Julia Brown, and

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Aaron Goldenberg. This reading list examines

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the tension between the high scientific value

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of dried bloodspot bio-banks and low public

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support for secondary research use of these

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without consent. Please also go to the website

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to join the ELSI scholar Directory, sign up for

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newsletters and other events like this one at

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eLSIhub.org. You can also get daily updates

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and news through our handle on Twitter.

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Now just for some quick housekeeping

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information. If you wish to use closed

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captioning, please turn on the CC button at the

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bottom of your screen. Just a reminder that

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panelists' presentations will be very brief in

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order to conserve a significant portion of our

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time in discussion. So please use the Q&A

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button, which you will find at the bottom of

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your screen, to write in questions for

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panelists. And you can do this at this point

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during our session.

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You can also register your enthusiasm for

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a question and elevate it up the list by using

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the upvote button in the Q&A box. The chat box

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is also available for further engagement. Know

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that we will post links to resources referenced

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in today's discussion there as well. And if at

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any time you have questions, please e-mail

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info@eLSIhub.org.

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Now it is my utmost pleasure to introduce

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our Forum moderator today, Natasha Bonhomme.

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Natasha Bonhomme brings nearly 15 years of

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nonprofit and maternal and child health

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experience to her role as Founder of Expecting

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Health. She launched Expecting Health to bring

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a range of consumer and professional

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stakeholders to address the need for clear,

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science-based information for families and

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individuals through tangible, actionable

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messages. Her focus is on bringing families'

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perspectives into policy and program design and

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implementation. Her programmatic portfolio

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includes leading Baby's First Test, a national

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resource center which reaches over 600,000

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families and health providers annually;

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convening the Perinatal Nutrition

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Collaborative, a coalition of organizations and

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nutrition experts that share emerging science

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and research efforts; and participating on

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numerous committees on maternal health and

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dignified care throughout the prenatal and

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postnatal periods. Ms. Bonhomme has also

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testified in front of Congress on the

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importance of family support and education on

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newborn screening. She is a board member of

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the D.C.-based Federally Qualified Health

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Center, Whitman-Walker Health, which provides

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affirming community-based care with a special

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focus on LGBTQ and HIV care.

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So please join me in welcoming

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Ms. Bonhomme. I'm delighted, ah, to hand it

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over to you.

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NATASHA BONHOMME: Thank you so much. It

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really is, ah, such an honor to be here and to

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introduce our panelists for today, Eric

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Hendrick and Professor Aaron Goldenberg.

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Eric Hendrix is a public health attorney

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and manager of the public health and legal

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services section at the Michigan Department of

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Health and Human Services. He has served as a

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public health attorney for five years, prior to

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which he was a law clerk for a U.S. magistrate

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judge. He supports a full range of public

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health programs, including communicable

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disease, chronic disease, and environmental

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health. He is a graduate of the University of

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Michigan Law School and has lectured on public

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health law at the U-M School of Public Health.

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Aaron Goldenberg is a professor and vice

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chair in the Department of Bioethics at the

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Case Western Reserve University School of

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Medicine. He is also codirector for the Case

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Western Center for Genetic Research Ethics and

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Law. Dr. Goldenberg has a background in

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bioethics, health behavior, health comm- --

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health education, public health ethics, and

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public health genetics. He has focused his

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work on the ethical, legal, and social issues

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associated with -- with the integration of new

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genomic technologies into research, clinical,

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and public health settings. Dr. Goldenberg's

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research program has been grounded by the

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number of major project areas, including the

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ethical and social implications --

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implementation of storing and using of

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biological specimens and data for research; the

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implications of genomic... of genomics on

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health disparities; and ethical implications of

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expanding newborn screening programs. He is

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currently cochair of the Newborn Screening

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Translational Research Network's Bioethics and

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Legal Workgroup, and cochair for the legal and

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legislative issues in Newborn Screening

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Workgroup for the Association of public health

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laboratories. So we really have two of the

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best speakers for this topic!

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It really is quite impressive how timely

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our conversation is today. While many know all

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of the successes surrounding the near 60-year

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history of newborn screening, few are fully

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aware of the legal battles state programs have

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faced over the past decade in regards to the

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secondary use of bloodspots. These bloodspots

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have been called more precious than gold, due

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to the fact that there isn't another specimen

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collection that so extensively captures an

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entire population -- anywhere from 98 to 99% of

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all babies born in the U.S. However, what

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we've always called the state's

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responsibilities to stewardship of these

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samples has been -- and I think many of us

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assume will continue to be -- challenged as

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actually... either potentially a breach of

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privacy, or potentially failure to -- of

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disclosure. But I think, simply put, just not

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including parents in the decision-making

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process around their children.

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And we are fortunate to be able to hear

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about the recent case in Michigan from Eric and

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the context of newborn screening research from

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Aaron. And I really encourage everyone not to

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see this as a one-off or just a newborn

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screening issue, or just a state issue, but

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potentially a warning to what ELSI research may

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be facing in the years to come, and think what

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could we, should we, what DO we need to be

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doing as our collective response.

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And with that, I will turn the floor over

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to my colleague, Eric!

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ERIC HENDRICKS: Hello, and good

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afternoon! Yes, Eric Hendricks. Thank you for

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the wonderful introduction, Natasha. Next.

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A bit of fine print upfront. So, this

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presentation is for informational purposes

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only. The interpretations are my own, and

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don't represent an official position. And

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additionally, MDHHS, I can only speak about

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publicly available information. We are still

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in the middle of litigation in the case, and so

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unfortunately I can't speculate. I'm going to

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give the kind of presentation I personally

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dislike, which is reading primarily from the

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slides, because that's the material that's

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available publicly. Nonetheless, I hope that I

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can give you some perspective on the

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litigation, and I hope that it may be of some

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use to you to be aware of what's out there.

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Additionally, of course, we don't establish an

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attorney-client relationship through this

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presentation, and this is not legal advice.

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Seek advice if you need it from your own

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counsel. Next, please.

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Disclosures. As noted, I'm an employee of

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the MDHHS, and I have no commercial interest to

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disclose. Next.

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Briefly, on MDHHS's newborn screening

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program: screens for over 55 disorders. Under

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law, in Michigan, a health professional MUST

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conduct newborn screening around the time of

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birth. Residual DBS, dried bloodspots, are

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retained by MDHHS for 35 years. And that I

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they're used for things like improving newborn

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screening and onboarding new tests. Next.

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The BioTrust program is Michigan's program

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using bloodspots. It is an IRB-approved

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research project established in 2010 to ensure

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the best use was made of residual bloodspots.

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Spots collected prior to 2010 are generally

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available for research via a waiver of informed

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consent, under a pre-2010 rule. We have a

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post-2010 rule where informed consent sought at

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time of birth. Parents can contact to opt out

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of research or direct return of dried

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bloodspots. Next.

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As to the case itself, it alleges

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violations of parents and newborn children's

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rights under the 14th Amendment, due process

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clause, and under 4th aimed, alleging a search

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and seizure violation. It also challenges

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newborn screening in its entirety without

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consent. There was a quote I wanted to pick on

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where it said, the plaintiff is alleging the

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reason they're arguing it's unconstitutional is

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because parents were never given the chance to

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decide whether they wanted their newborn's

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blood drawn in the first place. Additionally,

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it causes issues of retention, storage, and

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consent for research. It's alleged that,

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quote, research was intentionally sought during

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the birthing hospital stay when the parents

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failed to have a clear mind and make an

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informed decision, and it was thus, quote,

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false consent. Next.

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As to the sufficiency of consent -- to the

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court now. This is one of the recent court

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decisions. The court notes, without legal

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citation, some of the plaintiff parents argue

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that their consent was not voluntary because it

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was obtained within 24 hours of birth. Next.

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The Court said, it's clear that defendants

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do in fact retain the dried bloodspots and

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indefinitely store the samples for use by the

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state and third party researchers. As such,

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plaintiffs have not only alleged but proven

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that absent the parents' consent for research,

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defendants interfere with the fundamental right

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to direct care of children. Next.

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As to the waiver of informed consent under

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the Common Rule, the Court said even assume

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that the consent procedure in the Common Rule

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is sufficient for the purposes of due

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process -- an issue this Court does not

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decide -- MDHHS has not shown the four steps to

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ensure consent was received. Next.

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Again, the Court said besides the

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reference to the Common Rule, defendants

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provide no authority that an informed consent

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waiver from the IRB is sufficient to waive the

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constitutional requirement of informed parental

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consent. While this Court appreciates that

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MDHHS believed it followed federal law and

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sound medical ethics when it approved the

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waiver of informed consent, the question here

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is whether the consent valid to waive a

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parents' fundamental right to direct the

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medical care of their children. Next.

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The Court said defendants have NOT

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demonstrated that the waiver of informed

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consent by the IRB was constitutionally

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sufficient to conduct research on the

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children's DBS. Dried bloodspots. Next?

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The Court noted the factors under the

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Common Rule for the waiver of informed consent,

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the first of which is that the research must

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include no more than minimal risk to subjects;

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the second that the waiver will not adversely

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affect the rights and welfare of the subjects.

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The Court con colluded the waiver of informed

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consent WILL adversely affect the rights --

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their rights, because the blood is being used

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for research without their consent or consent

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offered by their parents. The Court further

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said pamphlets about the newborn screening

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program may have been at the hospital, but

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there is no record of whether the plaintiffs

00:14:59.000 --> 00:15:00.000

were aware of the program and therefore could

00:15:00.000 --> 00:15:03.000

object to the storage of research. Next.

00:15:03.000 --> 00:15:05.000

The third factor under the Common Rule is

00:15:05.000 --> 00:15:07.000

that the research could not be practicably

00:15:07.000 --> 00:15:10.000

carried out without the waiver or alteration.

00:15:10.000 --> 00:15:13.000

The Court said, the research CAN be practicably

00:15:13.000 --> 00:15:16.000

carried out without the waiver. Ah, and notes

00:15:16.000 --> 00:15:20.000

that in fact there were other dried bloodspots

00:15:20.000 --> 00:15:21.000

where consent HAD been obtained upon which the

00:15:21.000 --> 00:15:24.000

research could have been carried out. Next.

00:15:24.000 --> 00:15:26.000

Finally, fourth, the Common Rule provides

00:15:26.000 --> 00:15:28.000

that for waiver, whenever appropriate, the

00:15:28.000 --> 00:15:29.000

subjects must be provided with additional

00:15:29.000 --> 00:15:33.000

pertinent information after participation. And

00:15:33.000 --> 00:15:34.000

the Court... additionally stated that the

00:15:34.000 --> 00:15:37.000

couple of his testified that they did not know

00:15:37.000 --> 00:15:39.000

about the opportunity for destruction of dried

00:15:39.000 --> 00:15:41.000

bloodspots upon request prior to the lawsuit.

00:15:41.000 --> 00:15:44.000

Next.

00:15:44.000 --> 00:15:47.000

The Court thus applied strict scrutiny.

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Ah, which is a legal term meaning that the

00:15:49.000 --> 00:15:51.000

State must show that there's a compelling

00:15:51.000 --> 00:15:54.000

interest in its actions that it's carrying out,

00:15:54.000 --> 00:15:57.000

and that those actions have been narrowly

00:15:57.000 --> 00:16:00.000

tailored to that interest. The Court states,

00:16:00.000 --> 00:16:03.000

to the extent that State defendants conduct

00:16:03.000 --> 00:16:04.000

research or authorize others to conduct

00:16:04.000 --> 00:16:08.000

research on dried bloodspots to expand and

00:16:08.000 --> 00:16:10.000

strengthen the newborn screening program, such

00:16:10.000 --> 00:16:12.000

research advances a compelling interest. It is

00:16:12.000 --> 00:16:14.000

also narrowly tailored, as such research

00:16:14.000 --> 00:16:17.000

focuses exclusively on the -- on improving

00:16:17.000 --> 00:16:19.000

accuracy with test results or discovering new

00:16:19.000 --> 00:16:21.000

ways to identify life-threatening conditions.

00:16:21.000 --> 00:16:25.000

However, general public health research does

00:16:25.000 --> 00:16:29.000

NOT advance a compelling interest. Next?

00:16:29.000 --> 00:16:33.000

Again, reading from the Court's opinion:

00:16:33.000 --> 00:16:34.000

Defendants did not seek express consent to

00:16:34.000 --> 00:16:37.000

store the dried bloodspots. And the research

00:16:37.000 --> 00:16:39.000

conducted by the BioBank is NOT used solely to

00:16:39.000 --> 00:16:42.000

expand the newborn testing program, but for

00:16:42.000 --> 00:16:45.000

other public health research. Enhancing public

00:16:45.000 --> 00:16:47.000

health research is a laudable goal, and one

00:16:47.000 --> 00:16:50.000

that hopefully has success with dried

00:16:50.000 --> 00:16:52.000

bloodspots obtained from parents who HAVE given

00:16:52.000 --> 00:16:55.000

consent. To the extent that research is

00:16:55.000 --> 00:16:56.000

conducted for public health purposes not

00:16:56.000 --> 00:16:59.000

directly connected to the care of the newborn

00:16:59.000 --> 00:17:01.000

children, the practice fails to advance a

00:17:01.000 --> 00:17:06.000

compelling governmental interest. Next.

00:17:06.000 --> 00:17:10.000

As to where the case is presently, there

00:17:10.000 --> 00:17:14.000

are pending motions -- which is to say, still

00:17:14.000 --> 00:17:17.000

before the court and which yet to be decided.

00:17:17.000 --> 00:17:20.000

One issue -- one filed by couple of his,

00:17:20.000 --> 00:17:23.000

seeking reconsideration, essentially asking the

00:17:23.000 --> 00:17:26.000

court to rethink one of its decisions as to the

00:17:26.000 --> 00:17:33.000

sufficiency of consent. As I noted, the court

00:17:33.000 --> 00:17:36.000

found... The court declined the opportunity to

00:17:36.000 --> 00:17:38.000

find that the consent provided by the couple of

00:17:38.000 --> 00:17:40.000

his was sufficient in some way. So the couple

00:17:40.000 --> 00:17:43.000

of his are asking for reconsideration regarding

00:17:43.000 --> 00:17:44.000

that. And MDHHS still has a motion for

00:17:44.000 --> 00:17:47.000

reconsideration regarding the application of

00:17:47.000 --> 00:17:49.000

the Common Rule to waiver of informed consent,

00:17:49.000 --> 00:17:51.000

and asking the court to reconsider some of its

00:17:51.000 --> 00:18:04.000

conclusions on that. That's where we're at at

00:18:04.000 --> 00:18:05.000

present!

00:18:05.000 --> 00:18:07.000

AARON GOLDBERG: Thank you so much --

00:18:07.000 --> 00:18:09.000

(clears throat) Thank you so much, Eric. Um,

00:18:09.000 --> 00:18:12.000

I know that there are probably lots of

00:18:12.000 --> 00:18:14.000

questions related to the lawsuit, where it's

00:18:14.000 --> 00:18:18.000

been and where it's going, and we'll have a

00:18:18.000 --> 00:18:21.000

good amount of time to chat as, ah, as a group.

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I also just wanna say welcome to, to so many

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who have joined us this afternoon, or, or this

00:18:27.000 --> 00:18:30.000

morning, where, depending on where you are

00:18:30.000 --> 00:18:34.000

watching this video. Um. And it's great to

00:18:34.000 --> 00:18:36.000

see so many, ah, scholars -- (clears throat)

00:18:36.000 --> 00:18:39.000

And faculty and students and staff who have,

00:18:39.000 --> 00:18:42.000

ah, engaged in research and dialogue about

00:18:42.000 --> 00:18:44.000

these issues, really over the last 15, 20

00:18:44.000 --> 00:18:47.000

years. And so, I'm really looking forward to

00:18:47.000 --> 00:18:51.000

our conversation; I think it's gonna be really,

00:18:51.000 --> 00:18:54.000

ah, an amazing opportunity for us to talk about

00:18:54.000 --> 00:18:56.000

newborn screening research, the lawsuit, and

00:18:56.000 --> 00:19:02.000

what the potential implications for ELSI are.

00:19:02.000 --> 00:19:05.000

Um, I wanna kind of, ah... echo Natasha's

00:19:05.000 --> 00:19:09.000

thoughts about, you know, does this case in

00:19:09.000 --> 00:19:13.000

some ways act -- as I put it here -- as kind of

00:19:13.000 --> 00:19:14.000

a canary in a coal mine? Kind of a warning of

00:19:14.000 --> 00:19:16.000

what may be coming legislatively, in terms of

00:19:16.000 --> 00:19:18.000

policy and practice, both around newborn

00:19:18.000 --> 00:19:20.000

screening research but actually around research

00:19:20.000 --> 00:19:22.000

generally. And we'll talk a little bit about,

00:19:22.000 --> 00:19:25.000

through my presentation, what that might --

00:19:25.000 --> 00:19:28.000

what that might look like. You can go to the

00:19:28.000 --> 00:19:29.000

next slide. I have nothing to close. Go to

00:19:29.000 --> 00:19:31.000

the next slide.

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For many of you, this is, ah, second

00:19:32.000 --> 00:19:35.000

nature, something you've been studying for a

00:19:35.000 --> 00:19:38.000

long time. For those of you who may be new to

00:19:38.000 --> 00:19:40.000

newborn screening, state newborn screening

00:19:40.000 --> 00:19:43.000

programs have been around for a long time.

00:19:43.000 --> 00:19:45.000

We're coming up on 60 years, just in a year or

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two, from kind of the initiation of initial

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state newborn screening programs. So, these

00:19:52.000 --> 00:19:57.000

programs have been around for a long time.

00:19:57.000 --> 00:19:58.000

And, the various uses of, ah, various secondary

00:19:58.000 --> 00:20:00.000

uses of dried bloodspots have been around for a

00:20:00.000 --> 00:20:03.000

long time as well. It's really in kind of the

00:20:03.000 --> 00:20:06.000

last 15, 20 years that the questions have been,

00:20:06.000 --> 00:20:08.000

have arisen around the secondary uses. And so

00:20:08.000 --> 00:20:10.000

what I'd like to do is just kind of establish a

00:20:10.000 --> 00:20:12.000

little bit of a foundation for our conversation

00:20:12.000 --> 00:20:15.000

today and then go from there.

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Most states do use their dried bloodspots

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for, for quality improvement, quality

00:20:19.000 --> 00:20:22.000

assessment. This may be to develop a new test

00:20:22.000 --> 00:20:23.000

if a new condition has been added to a newborn

00:20:23.000 --> 00:20:26.000

screening panel. This may be to improve the

00:20:26.000 --> 00:20:29.000

assays that are currently on newborn screening,

00:20:29.000 --> 00:20:34.000

and to, ah, to improve the system generally.

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There are a number of states -- ah, this number

00:20:36.000 --> 00:20:37.000

changes slightly from year to year depending on

00:20:37.000 --> 00:20:40.000

state activities? But there are a number of

00:20:40.000 --> 00:20:44.000

states that do use dried bloodspots for

00:20:44.000 --> 00:20:46.000

research. Most of those states that use dried

00:20:46.000 --> 00:20:48.000

bloodspots for research do so under either an

00:20:48.000 --> 00:20:51.000

opt-out or destruction mechanism. What I mean

00:20:51.000 --> 00:20:53.000

by that is some states have an opt-out form

00:20:53.000 --> 00:20:55.000

that if parents choose to not want to have

00:20:55.000 --> 00:20:58.000

their child's sample used for research, they

00:20:58.000 --> 00:21:00.000

can sign an opt-out form, either at the

00:21:00.000 --> 00:21:02.000

hospital or online. I would say most states,

00:21:02.000 --> 00:21:04.000

though, have a mechanism for destruction. So

00:21:04.000 --> 00:21:06.000

if you'd rather not have your child's sample

00:21:06.000 --> 00:21:08.000

used for research, you can either call or

00:21:08.000 --> 00:21:11.000

e-mail the health department and have your

00:21:11.000 --> 00:21:13.000

sample destroyed. Two states, Michigan and

00:21:13.000 --> 00:21:15.000

Texas, do have a consent process in place, and

00:21:15.000 --> 00:21:17.000

we'll talk a little bit about that. And we

00:21:17.000 --> 00:21:19.000

thought it might be interesting to share a

00:21:19.000 --> 00:21:22.000

little bit of what the numbers look like in

00:21:22.000 --> 00:21:25.000

terms of who's consenting, who's declining or

00:21:25.000 --> 00:21:28.000

not signing the consent forms in those two

00:21:28.000 --> 00:21:30.000

states. It's important for me to note that

00:21:30.000 --> 00:21:34.000

these numbers really vary, I would say not just

00:21:34.000 --> 00:21:37.000

by -- I say here year by year? But they really

00:21:37.000 --> 00:21:40.000

vary month by month, and they vary by birthing

00:21:40.000 --> 00:21:42.000

center! So different hospital systems may see

00:21:42.000 --> 00:21:44.000

very different numbers. And we can talk a

00:21:44.000 --> 00:21:45.000

little bit about why that might be in our, in

00:21:45.000 --> 00:21:48.000

our discussion.

00:21:48.000 --> 00:21:51.000

In Michigan, generally, we see somewhere

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between 60 and 65% of parents consenting to

00:21:55.000 --> 00:21:58.000

allowing their samples to be put into the

00:21:58.000 --> 00:22:00.000

BioTrust? Again, that number drastically

00:22:00.000 --> 00:22:04.000

changes year to year, month to month, but

00:22:04.000 --> 00:22:07.000

that's been around the average. 15 to 20%

00:22:07.000 --> 00:22:10.000

decline storage and use of samples. And 15 to

00:22:10.000 --> 00:22:12.000

20% do not sign the form. Which because it's a

00:22:12.000 --> 00:22:14.000

consent process means those samples are not put

00:22:14.000 --> 00:22:16.000

into the BioTrust. In Texas, the numbers are a

00:22:16.000 --> 00:22:20.000

little different, a little lower in terms of

00:22:20.000 --> 00:22:21.000

who's consenting. So 35 to 40% generally

00:22:21.000 --> 00:22:25.000

consents to research. Around 15% have been

00:22:25.000 --> 00:22:27.000

declining. And somewhere between 40 and 50,

00:22:27.000 --> 00:22:29.000

again, depending on the month, depending on the

00:22:29.000 --> 00:22:31.000

year, are not signing the forms.

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And it's I think important to note that we

00:22:33.000 --> 00:22:35.000

don't have a LOT of information about the

00:22:35.000 --> 00:22:37.000

people -- the individuals who are not signing.

00:22:37.000 --> 00:22:40.000

It's possible they're not presented with the

00:22:40.000 --> 00:22:44.000

consent process; it's possible that see it and

00:22:44.000 --> 00:22:47.000

decide not to sign it, or, or -- you know,

00:22:47.000 --> 00:22:50.000

either way? Decline or consent? Um. But

00:22:50.000 --> 00:22:52.000

we'll talk a little about what the implications

00:22:52.000 --> 00:22:53.000

of that might be in, in a few minutes. Next

00:22:53.000 --> 00:22:58.000

slide?

00:22:58.000 --> 00:22:59.000

So, ah... I want na start our

00:22:59.000 --> 00:23:02.000

conversation, I wanna get us thinking, by

00:23:02.000 --> 00:23:04.000

establishing a little bit more about what

00:23:04.000 --> 00:23:06.000

lawsuits have been out there. So in addition

00:23:06.000 --> 00:23:08.000

to the lawsuit that we just heard about in

00:23:08.000 --> 00:23:11.000

Michigan, there have also been lawsuits in

00:23:11.000 --> 00:23:14.000

Texas, Minnesota, and Indiana. Um, they

00:23:14.000 --> 00:23:17.000

vary... on what these lawsuits are looking at!

00:23:17.000 --> 00:23:19.000

For example, the Minnesota lawsuit was really

00:23:19.000 --> 00:23:24.000

looking at whether or not the storage -- the

00:23:24.000 --> 00:23:25.000

collection and storage and research use of

00:23:25.000 --> 00:23:28.000

dried bloodspots violated genetic privacy

00:23:28.000 --> 00:23:32.000

legislation in the state. Other lawsuits,

00:23:32.000 --> 00:23:34.000

including Texas and Michigan, were looking at

00:23:34.000 --> 00:23:36.000

4th Amendment illegal search and seizure

00:23:36.000 --> 00:23:40.000

questions. And then as you just heard from

00:23:40.000 --> 00:23:41.000

Eric, the Michigan lawsuit's also looking at

00:23:41.000 --> 00:23:44.000

the veilings of the 14th Amendment in terms of

00:23:44.000 --> 00:23:46.000

due process to a right to direct the medical

00:23:46.000 --> 00:23:47.000

care of children. And we'll talk about that

00:23:47.000 --> 00:23:49.000

again in a second.

00:23:49.000 --> 00:23:52.000

So, why are we thinking that this is an

00:23:52.000 --> 00:23:54.000

important issue for ELSI, not just for newborn

00:23:54.000 --> 00:23:55.000

screening? First of all, I think some of the

00:23:55.000 --> 00:23:57.000

consent challenges in the lawsuit are

00:23:57.000 --> 00:24:02.000

concerning around challenging the validity of

00:24:02.000 --> 00:24:05.000

both an IRB and an OHRP-approved consent

00:24:05.000 --> 00:24:07.000

process, which Michigan HAS? It's gone through

00:24:07.000 --> 00:24:11.000

a lot of iterations, and a lot of public

00:24:11.000 --> 00:24:14.000

engagement, and dialogue with a number of IRBs.

00:24:14.000 --> 00:24:16.000

And Office of Human Research Protections. And

00:24:16.000 --> 00:24:18.000

so there's a little bit of a concern around

00:24:18.000 --> 00:24:20.000

kind of what judicial conversations about the

00:24:20.000 --> 00:24:24.000

validity of that consent might look like. And

00:24:24.000 --> 00:24:26.000

then, as we have been talking about quite

00:24:26.000 --> 00:24:29.000

frequently recently, the question of whether or

00:24:29.000 --> 00:24:32.000

not mothers can consent within 24 hours of

00:24:32.000 --> 00:24:34.000

birth raises a number of issues around the

00:24:34.000 --> 00:24:37.000

rights of women, the rights of mothers, to make

00:24:37.000 --> 00:24:39.000

decisions for themselves, for their families.

00:24:39.000 --> 00:24:42.000

And I think makes a lot of assumptions about

00:24:42.000 --> 00:24:44.000

what mothers can and can't do... after giving

00:24:44.000 --> 00:24:47.000

birth. So, I'd be interested in hearing some

00:24:47.000 --> 00:24:50.000

thoughts on that as well.

00:24:50.000 --> 00:24:53.000

As Eric talked about, the waiver of

00:24:53.000 --> 00:24:56.000

consent concerns, I think, have the potential

00:24:56.000 --> 00:24:58.000

to not just impact newborn screening research?

00:24:58.000 --> 00:25:00.000

I think that challenging the validity of a

00:25:00.000 --> 00:25:03.000

waiver could spill over into lots of other

00:25:03.000 --> 00:25:05.000

areas of research, and impact current

00:25:05.000 --> 00:25:09.000

regulatory frameworks NOT just for newborn

00:25:09.000 --> 00:25:12.000

screening, but for lots of research areas. And

00:25:12.000 --> 00:25:14.000

I have some major concerns about the potential

00:25:14.000 --> 00:25:18.000

of invalidating a waiver of consent in this

00:25:18.000 --> 00:25:22.000

case, and what that might mean for... waivers

00:25:22.000 --> 00:25:25.000

of consent generally. In pediatric research,

00:25:25.000 --> 00:25:26.000

in newborn research, but also in other areas as

00:25:26.000 --> 00:25:28.000

well.

00:25:28.000 --> 00:25:33.000

You can go to the next slide?

00:25:33.000 --> 00:25:37.000

So, the other issue at -- in this case is

00:25:37.000 --> 00:25:41.000

while initially the case did, ah, raise

00:25:41.000 --> 00:25:43.000

questions about the kind of public health

00:25:43.000 --> 00:25:45.000

screening itself, I think as the case has

00:25:45.000 --> 00:25:47.000

progressed and focused more on the research

00:25:47.000 --> 00:25:49.000

uses of the samples -- you can click to the

00:25:49.000 --> 00:25:51.000

next little animation -- I think that, um,

00:25:51.000 --> 00:25:56.000

there's some blurred lines happening here,

00:25:56.000 --> 00:25:59.000

where I think the court and the, and the couple

00:25:59.000 --> 00:26:00.000

of his are in some ways blurring the lines

00:26:00.000 --> 00:26:04.000

between the public health screening activities

00:26:04.000 --> 00:26:05.000

and other activities -- quality

00:26:05.000 --> 00:26:08.000

assessment/improvement, research. And so the

00:26:08.000 --> 00:26:10.000

idea of a violation of their right to direct

00:26:10.000 --> 00:26:13.000

medical care raises some questions around...

00:26:13.000 --> 00:26:15.000

how do you make the distinction between public

00:26:15.000 --> 00:26:18.000

health screening and other activities? Now,

00:26:18.000 --> 00:26:20.000

let me also just say that the blurred lines

00:26:20.000 --> 00:26:22.000

between quality improvement and quality

00:26:22.000 --> 00:26:24.000

assessment and pilot studies and research has

00:26:24.000 --> 00:26:27.000

already been in place in newborn screening for

00:26:27.000 --> 00:26:29.000

a long time. For those of us on the call who

00:26:29.000 --> 00:26:31.000

do a lot of work in newborn screening research,

00:26:31.000 --> 00:26:33.000

there's always been this kind of question of

00:26:33.000 --> 00:26:36.000

where do you draw the line. Is it generation

00:26:36.000 --> 00:26:38.000

of new knowledge? Is it who's doing the

00:26:38.000 --> 00:26:39.000

research, between kind of newborn screening

00:26:39.000 --> 00:26:41.000

research and newborn screening quality

00:26:41.000 --> 00:26:43.000

assessment and improvement? And I think

00:26:43.000 --> 00:26:45.000

there's a lot of work to be done in discerning

00:26:45.000 --> 00:26:51.000

the differences and thinking about what it

00:26:51.000 --> 00:26:52.000

means to have these different activities happen

00:26:52.000 --> 00:26:54.000

with dried bloodspots post-screening. But I

00:26:54.000 --> 00:26:56.000

think for me, and I think for many of us, this

00:26:56.000 --> 00:26:58.000

lawsuit is raising these questions again on how

00:26:58.000 --> 00:27:00.000

do you think about the kind of ethical

00:27:00.000 --> 00:27:04.000

implications of these distinctions, and where

00:27:04.000 --> 00:27:06.000

do we draw particular lines in terms of ethical

00:27:06.000 --> 00:27:11.000

justification, for example, for mandatory

00:27:11.000 --> 00:27:13.000

screening... versus uses of samples afterwards.

00:27:13.000 --> 00:27:18.000

Next slide?

00:27:18.000 --> 00:27:20.000

So, I wanna take one just very quick step

00:27:20.000 --> 00:27:23.000

back and say that we're focusing today on a

00:27:23.000 --> 00:27:25.000

state law, state issue, on a state lawsuit.

00:27:25.000 --> 00:27:27.000

But that actually, some of this, some of these

00:27:27.000 --> 00:27:31.000

debates are not restricted just to state

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litigation. Many of you know that the Newborn

00:27:32.000 --> 00:27:36.000

Screening Saves Lives Act, which was

00:27:36.000 --> 00:27:39.000

reauthorized in 2014, this is a law that

00:27:39.000 --> 00:27:42.000

provides a variety of resources and support

00:27:42.000 --> 00:27:47.000

for... federal newborn screening activities at

00:27:47.000 --> 00:27:51.000

the CDC, NIH. Ah, it s- -- it authorize the

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secretary's advisory committee on heritable

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disorders in newborns and children, and

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provides a number of resources for improving

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newborn screening and supporting newborn

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screening programs across the country. In

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2014, this law was, ah, reauthorized with an

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additional... what was in kind of Section 12,

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is what many of us know it -- have come to know

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it as. But a section of the law that redefined

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newborn screening bloodspots as being

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inherently -- not just identifiable, but

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inherently human subjects, thus requiring

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consent for all research uses. Ah, this

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policy... was hotly contested, hotly debated.

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Because it did put the brakes on a number of

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areas of newborn screening and research because

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of this definition. As you all know, directly

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after that, there were a number of Common Rule

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revisions. And one part of the Common Rule

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revisions is that it nullified this part of the

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Newborn Screening Saves Lives Act. So, under

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the final rule, secondary research with

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non-identified newborn screening bloodspots

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should be treated the same way as secondary

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research with any other kind of non-identified

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bio-specimen. This was a really big deal,

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because it reestablished the idea that newborn

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screening bloodspots shouldn't be treated

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differently than other kinds of bloodspots.

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The Newborn Screening Saves Lives Act is up for

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reauthorization right now and has been stuck in

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committee, ah, because of a variety of

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resistance from the U.S. Senate, which is

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adding kind of new challenges to bloodspot use.

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Wanting to go back and redefine bloodspots

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again as somehow being different than other

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bio-specimens requiring consent. So currently,

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the newborn screening saves lives

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reauthorization act is kind of on hold, with c-

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-- debates and conversations around what to do

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about research uses of samples. So this is not

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just a state issue, this is actually a federal

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issue as well. Next slide?

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So, um, I wanna raise one other issue in

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terms of kind of our ELSI considerations, which

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is one of equity and stewardship. Right? As

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many of you are aware, dried bloodspots

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represent a really unique collection of

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biological samples, given that they represent

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the entire state. Right? 4 million babies

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screened every year. And so in terms of trying

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to create resources that are representative,

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that include diverse communities, dried

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bloodspots are a really wonderful source of, of

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research resources...! That can be used in a

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variety of research areas, including improving

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newborn screening, including public health

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research, but also other kinds of genetic and

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health research! This is, in many ways, a

00:30:32.000 --> 00:30:36.000

wonderful opportunity to address what has been

00:30:36.000 --> 00:30:39.000

long discussed as a... deficiency in research

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nationally around including diverse

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communities. And so, this is really a, a rich

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resource. Litigation, however, may impact

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consent waivers, and potentially leading to

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destruction of samples, as it did in a number

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of the other lawsuits -- in Minnesota and

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Texas, led to destruction of millions of

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samples. That may make it more difficult to

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utilize these samples. And so one of the other

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things that I think about a lot, and that I

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think we need to be considering, is what are

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the ethics of destroying these samples, in

00:31:10.000 --> 00:31:13.000

terms of supporting research that is more

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equitable, more inclusive and more diverse.

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That being said, I think it's also time for us

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to better understand the perspectives of what I

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call decliners and no signers. And not because

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I believe we should be getting them all to say

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yes and that our goal is getting everyone to

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participate. But because I think it's

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important to better understand why a family,

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why individuals might not want their children's

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samples to be used in research. To improve

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education; to improve outreach and dialogue; to

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improve transparency of how samples are used.

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And so I think we need to be thinking about how

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do we become better stewards of these -- of

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this wonderful resource! In ways that

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respect... individual choices, but also promote

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good science, and promote good science using

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these samples. Next slide?

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And part of that is acknowledging that

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there are many changes in societal views and

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values related to research, related to who has

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your information, related to data. This

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picture on the, on the left-hand side is from

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the Minnesota lawsuit. If you can't see it --

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it's a little small -- this little child has a

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shirt that says "help, my -- the government has

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my DNA." So this is accompanying an increase

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kind of lack of trust in government agencies,

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and potential concerns over who has your

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information. At the same time, another example

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is that we're seeing -- and I think, thankfully -- a recognition of injustices that

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have been done, especially in marginalized

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communities, through research in history. And

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what that means for current research

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participants. How do we respect the rights of

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current research participants? How do we make

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sure we're addressing past injustices, making

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sure that we're thinking about disparities and

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inequity in research? And, and thinking about

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how do we create policies that are both

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equitable, in terms of collection and storage

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and use of samples, but the benefits of

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those -- of that research as well. Next slide?

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So here's where I wanna, I wanna kind of

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finish off. Which is to say I think that

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sometimes these debates can lead to what I'm

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kinda calling a false dichotomy between

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balancing parental control and benefits. That

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on one hand we either give parents complete

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control and, and that's gonna reduce the

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ability to use these samples 'cause many people

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may say no, versus hey, we can just use these

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samples with an opt-out and then we'll have a

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really robust resource. And I think we need to

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move away from this dichotomy. We need to

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think about both balancing parental permission

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and the benefits of secondary use? And what

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that means for me, as an ELSI scholar, as

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someone who works in this area, is to think

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about the distinctions between enhanced

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parental consent -- how do we do consent

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better? How do we do it in more meaningful

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ways? How do we recognize the needs of various

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communities? Um, AND! Also recognize that

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right now, from a regulatory perspective,

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opt-out is acceptable...! And, um, how do we

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do that in an informed way? How do we make

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sure that there's dialogue? How do we make

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sure there's discussion?

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And so if you go to the next slide, this

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is where I'll end, and this is where I'd love

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to open it up to our conversation, which is:

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If we think about what's ethically permissible,

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I think we can make arguments that both opt-in

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consent and opt-out may be from a regulatory

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perspective permissible. But I think, given

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these lawsuits and issues, we need to consider

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other things. We need to be thinking about

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balancing individual, community and scientific

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value. We need to be thinking about public

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trust in newborn screening and the public

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health system. If by taking away consent or,

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um, by having a lack of transparency about how

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samples are used, if we not only hurt trust in

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the public health system but potentially hurt

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trust in the newborn screening system, that's

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highly problematic. We need to maintain the

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benefits of the newborn screening system. We

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at the same time need to consider promoting

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diversity in participation, and in our

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research. We need to address past experiences

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with research and health care inequalities, and

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what that means for participation. And

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finally, we need to think about the impact that

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further litigation -- including this lawsuit --

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may have on research, public health programs.

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And, for me, I think we need to be talking

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about transparency, communication, and

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education, and increasing all three, in order

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to create a better... dialogue about the, the

00:35:23.000 --> 00:35:25.000

uses of these samples.

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So here are just two questions that I

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wanna end with and pose to all of you. Which

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is: We know what may be ethically permissible;

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what do we think is ethically recommended here?

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How do we move forward? And then finally, how

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might current lawsuits prepare us for possible

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future challenges to NOT just newborn

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screening, but wider research policies and

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practices? And so I hope that in our

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discussion, we can talk a little bit about

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newborn screening research, but also about what

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this lawsuit may mean for the ELSI of research

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generally and human subject protections.

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So I will end there. You can go to our

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next slide. Thank you so much to the eLSIhub,

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and to collaborators on various projects. This

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is my daughter getting her newborn screening.

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I did get her consent this morning, ah, to show

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it. She was a little embarrassed, but she

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said, "okay!! It's fine." So! Looking

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forward to a great conversation and talking

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with all of you.

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NATASHA BONHOMME: Great. Thank you so

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much, Eric and Aaron. We have a number of

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questions that have come in from the audience.

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So we will actually start there. Let me see.

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Ah, I think this is a question just for all of

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our panelists. Are there existing models to

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have community members guide, determine, or

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influence some of the research that is done on

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samples? Do community members get to help come

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up with research questions that researchers ask

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them to use genetic samples? How do we engage

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and partner with communities in, in research?

00:36:59.000 --> 00:37:01.000

AARON GOLDBERG: Yeah, that's a fantastic

00:37:01.000 --> 00:37:03.000

question. Eric, I don't -- you want me to

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start, and then I can pass it on to you?

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ERIC HENDRICKS: The only thing that I was

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going to note is that there IS the BioTrust

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community's advisory board, which was

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established at the time of the BioTrust to

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assist in gaining community perspective and

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ensuring that was reflected by the program.

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But I don't think there's much more that I can

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say on the topic, so I'll defer to you.

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AARON GOLDBERG: Yeah, that's exactly what

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I was going to say, is Michigan is a great

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example. They have this advisory board that's

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been around since the inception of the

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BioTrust, and has helped to shape the consent

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process, the kind of research that's being

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done, the public messages, the public

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engagement. In addition to the advisory board,

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Michigan -- and other states -- have done a

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variety of community engagement activities.

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Michigan held kind of town hall meetings all

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over the state, to talk about both the

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establishment of the BioTrust and what samples

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might be used for. I think states, ah, who

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have used blood samples have done a, I think, a

00:38:01.000 --> 00:38:04.000

good job of trying to engage, trying to do

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research and engagement around these issues.

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Are there ways that it could be improved? I

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think so! I think there are things that could

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be done to involve community members and...

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donors, or sources of samples, more frequently?

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In decisions around how samples are used? Um.

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And to do a better job kind of, in some ways,

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maybe returning both individual -- but, most

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likely, aggregate -- results to families. And

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give them kind of more input and ability to

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interact with the program. But great question.

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NATASHA BONHOMME: Great. Um... I'm

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trying to make sure not to be too repetitive in

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some of the questions. Are there any efforts

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to get more data on how the consent

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requirements affect the diversity and

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representativeness of the banked samples? One

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of the things I said when we first opened is

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that one of the things that people find so

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valuable is that this really is such a snapshot

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of the population, as is now. And we have to

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say, partially because it's just done

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routinely. And so what does that affect of

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having more of a conversation and consent have

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on that?

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AARON GOLDBERG: Yeah, that's another

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great question. And I'll say that, yes, I

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think a number of states are investigating

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spending more time looking at decliners.

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Talking to hospital systems to try to assess...

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who's consenting, who's not. What are

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potential systematic barriers to DOING the

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consent process? I also want to mention -- I

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meant to mention before -- there are a number

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of research, ELSI research teams around the

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country doing I think really important research

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in this area. Myself and Rothwell at the

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University of Utah are working with Michigan on

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a number of activities to better understand

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concerns of various communities around the use

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of these samples. There's an interdisciplinary

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institutional team in California with UCSF,

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Stanford, and Berkeley working on a number of

00:40:04.000 --> 00:40:08.000

these issues and doing really amazing work

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thinking about consent and newborn screening

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issues and public opinions. So I think there's

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work going on; I think more has to come,

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because I think we don't have all the answers

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for, you know, whether or not those decliners

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and... no-signers are leading to long-term,

00:40:25.000 --> 00:40:28.000

um... discrepancies in who's saying yes and

00:40:28.000 --> 00:40:32.000

who's saying no, or potential biases in the

00:40:32.000 --> 00:40:34.000

sample. I think there's, um, SOME evidence out

00:40:34.000 --> 00:40:37.000

there, but I think there needs to be more to

00:40:37.000 --> 00:40:40.000

show whether or not there are kind of

00:40:40.000 --> 00:40:44.000

systematic long-term biases being introduced to

00:40:44.000 --> 00:40:45.000

these resources based on who's saying yes and

00:40:45.000 --> 00:40:47.000

no to the research.

00:40:47.000 --> 00:40:50.000

ERIC HENDRICKS: I would just add onto

00:40:50.000 --> 00:40:53.000

that very briefly, quoting from the court's

00:40:53.000 --> 00:40:55.000

most recent order: that defendants explained

00:40:55.000 --> 00:41:01.000

13% of mothers receive inadequate prenatal

00:41:01.000 --> 00:41:05.000

care, and it's impractical to collect consent

00:41:05.000 --> 00:41:07.000

forms from the more than 80 prenatal care

00:41:07.000 --> 00:41:08.000

centers as opposed to hospitals in Michigan.

00:41:08.000 --> 00:41:11.000

NATASHA BONHOMME: Thank you for that.

00:41:11.000 --> 00:41:15.000

Who is driving the Newborn Screening Saves

00:41:15.000 --> 00:41:17.000

Lives Act? It's impressive it has such

00:41:17.000 --> 00:41:20.000

prominent federal attention. Maybe I'll gear

00:41:20.000 --> 00:41:21.000

that towards Aaron, and I'm always happy to add

00:41:21.000 --> 00:41:22.000

in --

00:41:22.000 --> 00:41:23.000

AARON GOLDBERG: Yeah, do you want to

00:41:23.000 --> 00:41:25.000

start? You're probably even better at

00:41:25.000 --> 00:41:27.000

answering this one! (chuckles)

00:41:27.000 --> 00:41:30.000

NATASHA BONHOMME: Sure! So, you know,

00:41:30.000 --> 00:41:32.000

the Newborn Screening Saves Lives Act has a

00:41:32.000 --> 00:41:34.000

long history. And it really has been a

00:41:34.000 --> 00:41:37.000

collaborative effort amongst a number of

00:41:37.000 --> 00:41:44.000

advocacy organizations -- both national ones

00:41:44.000 --> 00:41:48.000

such as, um, March of Dimes, Genetic Alliance;

00:41:48.000 --> 00:41:51.000

now Every Life Foundation -- as well as

00:41:51.000 --> 00:41:52.000

disease-specific organizations? As WELL as

00:41:52.000 --> 00:41:55.000

professional societies, such as the American

00:41:55.000 --> 00:41:58.000

College of Medical Genetics. So there are a

00:41:58.000 --> 00:42:00.000

number -- AND also the Association of Public

00:42:00.000 --> 00:42:02.000

Health Laboratories. So there are, it IS

00:42:02.000 --> 00:42:04.000

definitely a multi-stakeholder approach? And,

00:42:04.000 --> 00:42:09.000

um. There are a lot of different things that

00:42:09.000 --> 00:42:12.000

ARE tied to that, um... to that legislation.

00:42:12.000 --> 00:42:16.000

Including... most of the federally-funded

00:42:16.000 --> 00:42:18.000

newborn screening efforts. Um, are tied, at

00:42:18.000 --> 00:42:23.000

least in some way, to that legislation. So,

00:42:23.000 --> 00:42:24.000

um. That is how it has all that... attention.

00:42:24.000 --> 00:42:30.000

AARON GOLDBERG: I'll also add that I

00:42:30.000 --> 00:42:33.000

think... the initial, um, reauthorization in

00:42:33.000 --> 00:42:37.000

2014 happened simultaneously to debates

00:42:37.000 --> 00:42:41.000

around... the revisions to the Common Rule.

00:42:41.000 --> 00:42:42.000

And given that many of the questions around the

00:42:42.000 --> 00:42:47.000

newborn screening saves lives reauthorization

00:42:47.000 --> 00:42:51.000

act were about the identifiability of

00:42:51.000 --> 00:42:52.000

bloodspots, and whether or not bloodspots

00:42:52.000 --> 00:42:55.000

constituted a human subject or not a human

00:42:55.000 --> 00:42:57.000

subject if used in a way that they were not

00:42:57.000 --> 00:42:59.000

identifiable -- which was at the same time

00:42:59.000 --> 00:43:01.000

being asked by the individuals and groups and

00:43:01.000 --> 00:43:03.000

organizations looking at the revisions to the

00:43:03.000 --> 00:43:09.000

Common Rule -- that particular law got a lot of

00:43:09.000 --> 00:43:13.000

attention... because it was a, in some ways, a

00:43:13.000 --> 00:43:16.000

legislative example of the complexities of this -- of these questions. Around

00:43:16.000 --> 00:43:18.000

identifiability, and what's a s- -- what's a

00:43:18.000 --> 00:43:21.000

human subject and what's not. So I think if

00:43:21.000 --> 00:43:23.000

you look at the dialogue around the Common Rule

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revisions, a lot of it did center on this law

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being an example of these kinds of samples

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maybe being called out as somehow different.

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And I think that's starting to come back.

00:43:33.000 --> 00:43:39.000

Because now the Common Rule's been -- they have

00:43:39.000 --> 00:43:42.000

been amended... ah, and, um, non-identifiable

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samples did not become identifiable or, or get

00:43:46.000 --> 00:43:50.000

defined identifiable, in the new Common Rule.

00:43:50.000 --> 00:43:53.000

The concern is that this RE-reauthorization --

00:43:53.000 --> 00:43:55.000

I don't know... (chuckles) Second

00:43:55.000 --> 00:43:57.000

reauthorization. Ah, might reignite some of

00:43:57.000 --> 00:44:00.000

these debates. And that's another reason why I

00:44:00.000 --> 00:44:02.000

think it's gotten a lot of attention, is that

00:44:02.000 --> 00:44:06.000

it's kind of reigniting some of the exact same

00:44:06.000 --> 00:44:09.000

debates we were having in 2015, 2016 around the

00:44:09.000 --> 00:44:15.000

Common Rule, about how we treat... BioBank

00:44:15.000 --> 00:44:17.000

samples! And what that looks like. And, yeah.

00:44:17.000 --> 00:44:23.000

NATASHA BONHOMME: Great. Have there been

00:44:23.000 --> 00:44:24.000

other instances or scenarios where the suf- --

00:44:24.000 --> 00:44:27.000

sufficiency of consent has been questioned?

00:44:27.000 --> 00:44:29.000

And is there any guidance for newborn screening

00:44:29.000 --> 00:44:33.000

programs on how they can help ensure

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documentation of sufficient consent to, to help

00:44:39.000 --> 00:44:41.000

mitigate this in the future?

00:44:41.000 --> 00:44:44.000

AARON GOLDBERG: Yeah, Eric, do you -- I

00:44:44.000 --> 00:44:45.000

don't know if you wanna.

00:44:45.000 --> 00:44:46.000

ERIC HENDRICKS: I don't know if I know --

00:44:46.000 --> 00:44:49.000

if I recall enough about the Minnesota and

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Texas... suit allegations to speak to those.

00:44:51.000 --> 00:44:52.000

So I'll defer again.

00:44:52.000 --> 00:44:54.000

AARON GOLDBERG: Yeah, the Texas lawsuit

00:44:54.000 --> 00:44:56.000

happened BEFORE they established a consent

00:44:56.000 --> 00:45:00.000

process? And so, in fact, the consent process

00:45:00.000 --> 00:45:02.000

there -- it was in part a result of the ongoing

00:45:02.000 --> 00:45:04.000

litigation that was happening there. So

00:45:04.000 --> 00:45:07.000

because that lawsuit happened afterwards, I

00:45:07.000 --> 00:45:11.000

think this is really the first lawsuit that has

00:45:11.000 --> 00:45:13.000

happened in a state, post starting screening --

00:45:13.000 --> 00:45:15.000

again, we only have two states that are

00:45:15.000 --> 00:45:18.000

currently using an informed consent process.

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And I think it... I mean, I think it IS

00:45:20.000 --> 00:45:23.000

important for us to be thinking -- as an ELSI

00:45:23.000 --> 00:45:25.000

community, as a research community, as a

00:45:25.000 --> 00:45:28.000

newborn screening community -- about how do we

00:45:28.000 --> 00:45:31.000

try to create a consent process that is...

00:45:31.000 --> 00:45:37.000

usable across 80 or more birthing centers that,

00:45:37.000 --> 00:45:40.000

that happens, you know, all -- you know... um,

00:45:40.000 --> 00:45:42.000

you know, across hundreds of thousands of

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births every year. And, and to do so in a way

00:45:46.000 --> 00:45:48.000

that supplies enough information and enough,

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you know, dialogue with parents to make an

00:45:51.000 --> 00:45:58.000

informed decision? And at the same time be

00:45:58.000 --> 00:46:00.000

efficient; be, ah, and... allow for kind of...

00:46:00.000 --> 00:46:03.000

centralized, or decentralized, depending on how

00:46:03.000 --> 00:46:07.000

you look at it, control over that consent. And

00:46:07.000 --> 00:46:09.000

support for that consent process. Ah, we're

00:46:09.000 --> 00:46:11.000

not talking about just one health system or one

00:46:11.000 --> 00:46:13.000

research study; we're talking about... 80 or

00:46:13.000 --> 00:46:17.000

MORE research -- ah, research sites, if you

00:46:17.000 --> 00:46:20.000

will. They're not, you know -- birthing

00:46:20.000 --> 00:46:21.000

centers. And so I think that's important to,

00:46:21.000 --> 00:46:25.000

to recognize, and to think about how do you do

00:46:25.000 --> 00:46:29.000

that in a way that does that. Um, I, I

00:46:29.000 --> 00:46:31.000

think... this lawsuit is unique in that way, in

00:46:31.000 --> 00:46:33.000

that it does, um, address and kind of talk

00:46:33.000 --> 00:46:36.000

about the sufficiency of consent. And I think

00:46:36.000 --> 00:46:38.000

it... regardless of the outcome, I think it

00:46:38.000 --> 00:46:40.000

raises an important conversation that the

00:46:40.000 --> 00:46:42.000

newborn screening community has to have, and

00:46:42.000 --> 00:46:44.000

that maybe the ELSI community can have as well,

00:46:44.000 --> 00:46:47.000

which is: How do we think about consent in

00:46:47.000 --> 00:46:48.000

this context?

00:46:48.000 --> 00:46:51.000

NATASHA BONHOMME: Great. Thank you. I

00:46:51.000 --> 00:46:54.000

see there are a number of questions coming in,

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both on the Q&A side and the chat. If you put

00:46:56.000 --> 00:47:00.000

your question in the chat, if you could please

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put it into the Q&A section, that'll be easier

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for us to try to get to all of them.

00:47:07.000 --> 00:47:09.000

At some point, could people consider

00:47:09.000 --> 00:47:12.000

whether it is legal or ethical for parents to

00:47:12.000 --> 00:47:14.000

consent their babies' genetic data to be

00:47:14.000 --> 00:47:18.000

obtained and utilized for research? Parents

00:47:18.000 --> 00:47:21.000

can consent to children's health care, but what

00:47:21.000 --> 00:47:24.000

right do they have to allow access to detailed

00:47:24.000 --> 00:47:29.000

genetic information about their children for

00:47:29.000 --> 00:47:31.000

general research purposes? Any comments on

00:47:31.000 --> 00:47:32.000

that?

00:47:32.000 --> 00:47:33.000

AARON GOLDBERG: (chuckles)

00:47:33.000 --> 00:47:34.000

ERIC HENDRICKS: There's a couple of

00:47:34.000 --> 00:47:36.000

quotes, I believe, in the most recent court

00:47:36.000 --> 00:47:39.000

decision there. So I'm going to try to find

00:47:39.000 --> 00:47:40.000

those. And if you want to speak, I'll --

00:47:40.000 --> 00:47:42.000

AARON GOLDBERG: Yeah, if you pull those

00:47:42.000 --> 00:47:46.000

up, that would be great. And I guess I would

00:47:46.000 --> 00:47:47.000

say, we DO allow families to consent for their

00:47:47.000 --> 00:47:50.000

children. Ah, for general research purposes.

00:47:50.000 --> 00:47:53.000

That's been... that's been a, a regular kind of

00:47:53.000 --> 00:47:56.000

research practice for a long time. We do try

00:47:56.000 --> 00:47:58.000

to, as much as possible, as children grow older

00:47:58.000 --> 00:48:02.000

and can start making decisions for themselves,

00:48:02.000 --> 00:48:05.000

involve them in that process... through assent?

00:48:05.000 --> 00:48:07.000

And then, in many cases, give them options to

00:48:07.000 --> 00:48:10.000

choose to either continue participating or

00:48:10.000 --> 00:48:15.000

cease participating once they, ah, reach an age

00:48:15.000 --> 00:48:17.000

of majority. I think that... that would

00:48:17.000 --> 00:48:20.000

include genetic research; that would include

00:48:20.000 --> 00:48:24.000

research that collects genetic data. Um, I

00:48:24.000 --> 00:48:27.000

think that does raise some questions about, um,

00:48:27.000 --> 00:48:30.000

ongoing use of data? And whether or not

00:48:30.000 --> 00:48:35.000

children should have a right to, um, be either

00:48:35.000 --> 00:48:36.000

re- -- I don't know if it's called

00:48:36.000 --> 00:48:38.000

re-consented, but consented once they reach the

00:48:38.000 --> 00:48:40.000

age of majority, and there's a number of

00:48:40.000 --> 00:48:42.000

studies that have looked at that question? Ah,

00:48:42.000 --> 00:48:44.000

and I still think it's kind of an open area of

00:48:44.000 --> 00:48:47.000

dialogue for us, which is what to do with data

00:48:47.000 --> 00:48:49.000

that's not just used in a discrete place.

00:48:49.000 --> 00:48:53.000

Parents can consent to allow their children to

00:48:53.000 --> 00:48:56.000

participate in a BioBank. That's, that's

00:48:56.000 --> 00:48:59.000

allowed. But what do we do as those children

00:48:59.000 --> 00:49:02.000

grow is kind of an ongoing question in the ELSI

00:49:02.000 --> 00:49:04.000

community about... do we reply an assent

00:49:04.000 --> 00:49:06.000

process as they reach particular ages or

00:49:06.000 --> 00:49:09.000

particular levels of maturity? Or do we go

00:49:09.000 --> 00:49:11.000

back when they turn 18? And, and what does

00:49:11.000 --> 00:49:16.000

that mean for the establishment and ongoing

00:49:16.000 --> 00:49:18.000

stewardship of, of blood samples for research?

00:49:18.000 --> 00:49:20.000

Eric, do you wanna?

00:49:20.000 --> 00:49:24.000

ERIC HENDRICKS: Yeah. And Aaron, as you

00:49:24.000 --> 00:49:26.000

noted -- and thank you for doing so -- the

00:49:26.000 --> 00:49:27.000

plaintiffs allege in the court included that

00:49:27.000 --> 00:49:30.000

there is a fundamental right to direct the

00:49:30.000 --> 00:49:33.000

medical care of one's child. And so the court

00:49:33.000 --> 00:49:35.000

states... next question is whether if parents

00:49:35.000 --> 00:49:37.000

consented to research and/or storage of the

00:49:37.000 --> 00:49:39.000

dried bloodspots, if plaintiff parents

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consented, then there is no violation of a

00:49:42.000 --> 00:49:44.000

fundamental liberty interest. And, it is

00:49:44.000 --> 00:49:46.000

noteworthy, I think, that the court does

00:49:46.000 --> 00:49:52.000

distinguish between consent for search and

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consent for storage of the dried bloodspots.

00:49:53.000 --> 00:49:54.000

AARON GOLDBERG: Yeah, I think that was

00:49:54.000 --> 00:49:57.000

one of the things in this particular lawsuit

00:49:57.000 --> 00:49:59.000

that... raised some interesting questions, is

00:49:59.000 --> 00:50:03.000

they did try to separate out the storage and

00:50:03.000 --> 00:50:05.000

the, and the research use. Even though one may

00:50:05.000 --> 00:50:08.000

imply -- right, if you're storing -- if you're

00:50:08.000 --> 00:50:10.000

using them in future research studies, you need

00:50:10.000 --> 00:50:12.000

to be able to store them. And I think, um... I

00:50:12.000 --> 00:50:15.000

also wanna just say that I think one of the

00:50:15.000 --> 00:50:16.000

points you just raised, Eric, is an important

00:50:16.000 --> 00:50:20.000

one, which is I think one of the other unique

00:50:20.000 --> 00:50:21.000

things about this lawsuit is that... many of

00:50:21.000 --> 00:50:23.000

the plaintiffs -- and you can correct me if I'm

00:50:23.000 --> 00:50:27.000

wrong -- many of the plaintiffs did give

00:50:27.000 --> 00:50:31.000

consent! To, to... They signed the consent

00:50:31.000 --> 00:50:34.000

form, um, and gave consent for their newborn's

00:50:34.000 --> 00:50:36.000

sample to be put into the BioTrust. And so it

00:50:36.000 --> 00:50:39.000

raises a different set of questions than I

00:50:39.000 --> 00:50:41.000

think we've seen in Texas and Indiana and

00:50:41.000 --> 00:50:44.000

Minnesota. Which is, many of these plaintiffs

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did sign the consent process. So it's a very

00:50:45.000 --> 00:50:49.000

different set of questions, and raises a

00:50:49.000 --> 00:50:50.000

different set of, in some ways, ELSI concerns,

00:50:50.000 --> 00:50:52.000

than the previous lawsuits.

00:50:52.000 --> 00:50:55.000

ERIC HENDRICKS: That's quite true, Aaron.

00:50:55.000 --> 00:50:57.000

And it is noteworthy as well that I believe two

00:50:57.000 --> 00:50:59.000

of the plaintiff children were born prior to

00:50:59.000 --> 00:51:03.000

the introduction of the consent process of the

00:51:03.000 --> 00:51:05.000

BioTrust. Thus presenting difficulty.

00:51:05.000 --> 00:51:08.000

NATASHA BONHOMME: Thank you. Any

00:51:08.000 --> 00:51:11.000

thoughts on whole genome sequencing being used

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in newborn screening, and how that would change

00:51:15.000 --> 00:51:16.000

the legal approach to protecting that data?

00:51:16.000 --> 00:51:17.000

ERIC HENDRICKS: Aaron?

00:51:17.000 --> 00:51:20.000

AARON GOLDBERG: (laughs) I was gonna ask

00:51:20.000 --> 00:51:24.000

you if you wanted to start! Um. Yeah! I

00:51:24.000 --> 00:51:26.000

mean, I think this is, ah, a very important

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topic -- it's a topic that's being talked about

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a lot nationally right now? Um. I think that

00:51:33.000 --> 00:51:36.000

more and more newborn screening programs are

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thinking about in use of genomic technologies.

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Both either as an adjunct, or potentially,

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maybe down the road, as a replacement

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technology for certain screens? Nationally,

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this is also a big deal in terms of non-state

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newborn screening programs. Um, organizing and

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offering whole genome or, or whole exome

00:51:58.000 --> 00:52:02.000

sequencing for newborns in other clinical

00:52:02.000 --> 00:52:03.000

settings. For example, in a NICU setting or in

00:52:03.000 --> 00:52:06.000

other clinical settings.

00:52:06.000 --> 00:52:08.000

I think that... the area that this is

00:52:08.000 --> 00:52:10.000

going to impact, in terms of bloodspots and

00:52:10.000 --> 00:52:11.000

research, is that there have been a number of

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conversations within the revisions of the

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Common Rule about what different kinds of, um,

00:52:18.000 --> 00:52:20.000

regulatory mechanisms need to be in place, in

00:52:20.000 --> 00:52:22.000

terms of -- let's say, for example, what

00:52:22.000 --> 00:52:24.000

elements of consent need to be present when

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genome sequencing is done. And I think that

00:52:28.000 --> 00:52:30.000

states who are contemplating informed consent

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for bloodspot use will need to think about

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those conversations at the kind of federal

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regulatory level, in terms of what kinds of

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unique or new elements of consent need to be

00:52:42.000 --> 00:52:44.000

part of a consent process when sequencing may

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be done using samples. And that's, that's

00:52:49.000 --> 00:52:53.000

really where I think the most impact may be.

00:52:53.000 --> 00:52:56.000

Which is that as we're looking at refining and

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improving consent processes, or... dialogue

00:52:59.000 --> 00:53:01.000

with families about the use of samples, we need

00:53:01.000 --> 00:53:05.000

to be thinking about how, nationally, our

00:53:05.000 --> 00:53:07.000

regulatory structures are changing for the use

00:53:07.000 --> 00:53:10.000

of ANY kind of blood sample for genome

00:53:10.000 --> 00:53:12.000

sequencing, and what that might mean for

00:53:12.000 --> 00:53:19.000

bloodspot use and just kind of state consent

00:53:19.000 --> 00:53:20.000

and state information that is given to parents.

00:53:20.000 --> 00:53:23.000

NATASHA BONHOMME: Great. So if the

00:53:23.000 --> 00:53:27.000

failure to obtain consent is seen as adversely

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affecting the rights and welfare of subjects,

00:53:31.000 --> 00:53:35.000

would a waiver OF consent ever be considered

00:53:35.000 --> 00:53:36.000

acceptable?

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AARON GOLDBERG: ...say that one more

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time. If you don't mind. Sorry! (chuckles)

00:53:41.000 --> 00:53:44.000

NATASHA BONHOMME: If the failure to

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obtain consent is seen as adversely affecting

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the rights and welfare of a subject, would a

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waiver of consent EVER be considered

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acceptable?

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AARON GOLDBERG: I think from an ethical

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perspective, it COULD. I think that... I

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think from a regulatory and ethical

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perspective, a waiver is, is possible. Um.

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And I think a waiver might be, under certain

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circumstances -- under certain circumstances

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acceptable. However...! I worry that, um...

00:54:20.000 --> 00:54:22.000

that moving towards exclusively using waivers

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will potentially adversely affect the program

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generally, because of... individuals and

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families from communities who have been kind of

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adversely affected by research in the past may

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not adequately address issues around equity in

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terms of, um... you know, kind of historical

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injustice within research. I mean, I think no

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matter what, whether we're talking about a

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waiver or a consent process, I think education,

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dialogue, and transparency has to be increased.

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I think the question remains to be seen that if

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you were to increase dialogue, increase

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education, increase transparency... whether or

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not at that point a waiver is acceptable? I

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still think is a, is an open question. Because

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I think that for many parents -- especially

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parents potentially from marginalized

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communities who are concerned about the

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continuation of misuse of, ah, of data from

00:55:18.000 --> 00:55:20.000

their community -- would still want a consent

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process in place, would still want to be able

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to give consent. I think in a number of

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research studies we've seen... that parents

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wanna be able to give their permission. There

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have been a number of studies that have looked

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at parental acceptability of newborn screening

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bloodspot use. I think over and over again,

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those studies have shown higher levels of

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acceptance if permission is sought through a

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consent process. And I think we have to be

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thoughtful about that! So it's not that I

00:55:46.000 --> 00:55:48.000

think waivers are, are not possible...! I

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think that... waivers put us in a situation we

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have to be REALLY, really careful to not be, in

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some ways, shooting ourselves in the foot by on

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one hand increasing the number of people who

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are participating, increasing diversity of the

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samples, and at the same time potentially...

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continually, continuing kind of a legacy of

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potential harms to marginalized communities.

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So, I think there has to be that kind of, that

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balance. And I think that's where we really

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need to go with this.

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ERIC HENDRICKS: And I would just add to

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that by quoting again from the court's most

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recent decision on the motions for summary

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judgment. That besides the reference to the

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foregoing regulation -- which is to say the

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Common Rule's provision for waiver of informed

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consent -- defendants, meaning MDHHS and the

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other defendants, provide no authority that a

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waiver from the IRB is sufficient to waive the

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constitutional requirement of informed parental

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consent.

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AARON GOLDBERG: And Eric, correct me if

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I'm wrong, just to... My reading of that was

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that it was particularly referring to the idea

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of directing medical care for your child. And

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so I guess one of the questions -- and I don't

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know if this has come up and whether or not you

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can talk about it -- is: Does the research,

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does the storage and research use, is that seen

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differently? Or SHOULD that be seen

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differently, in terms of a waiver. Um. And

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whether or not that waiver of consent still

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violates a constitutional due process to...

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participation in research, versus directing

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medical care. I think -- I, I think... you

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know, some of the language that I saw in the

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lawsuit really related to the idea of directing

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medical care, the screening itself. So where

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do we draw that line, and where is that a

00:57:32.000 --> 00:57:34.000

blurred line in terms of what that means for

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research use.

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ERIC HENDRICKS: You're quite right that

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the court refers many times to fundamental

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right to direct the medical care of their

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children. So that certainly seems to be the

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manner in which the court is interpreting the

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research use.

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NATASHA BONHOMME: So I'm going to try to

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combine a couple of questions into one.

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Because we know I can't be on here and not

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mention anything about education! And where

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does that play into all of this. So, there are

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a number of comments and questions... basically

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saying, parents don't know this is happening.

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They're -- when WOULD be the right time to have

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an actual conversation and to do this

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consenting. In a real, deep way. And, um.

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One of the pieces that came up was, you know,

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yes, we've been talked about having... you

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know, consent being done after baby's born...!

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Family's in, in hospitals or in birthing

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centers settings. That not being maybe the

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BEST time. And, and suggestions around could

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consent, education... all of those good things,

00:58:49.000 --> 00:58:52.000

be done PRE-natally? And what are the

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hindrances to that? So I just thought, give

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you an opportunity to speak to that. Either,

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what may be feasible, what isn't feasible, what

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has been tried. And just your, your thoughts

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around that.

00:59:02.000 --> 00:59:03.000

ERIC HENDRICKS: I'll just say that we do

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have program personnel who are experts in this

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who work in newborn screening at BioTrust

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education. I'm not the right person to speak

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to that, but I can provide some of the

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materials that Michigan has prepared and uses

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in the chat, in case that's of any interest.

00:59:18.000 --> 00:59:19.000

NATASHA BONHOMME: Great. That'd be

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wonderful.

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AARON GOLDBERG: And I know we're running

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a little short on time. I'd just say briefly

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that a number of studies have shown interest in

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moving at least information about dried

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bloodspot use into the prenatal period and

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possibly consent into the prenatal period. I

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think the barriers to that have to do with kind

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of ongoing distinctions between pre- and

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postnatal issues. And I think we have to think

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about bridges across the period, both pre- and

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postnatal, where we move decisions into -- we

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don't talk a lot about screening, in the

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prenatal time period. And maybe we should do

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more. But that's increasing. And I think we

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can do more to bridge those time periods in

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ways that give parents more opportunities to

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listen, to talk, to ask questions. And to

01:00:12.000 --> 01:00:18.000

potentially consent! And to think about this

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as a spectrum, not just a pre and a post.

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Think about many parents, that birth experience

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is a spectrum from pre- to postnatal, and we

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can have that conversation at various times in

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that period.

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NATASHA BONHOMME: Great, thank you. I

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think I will now send it back to the team!

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Thank you so much to our panelists for a great

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conversation.

01:00:37.000 --> 01:00:40.000

SANDRA SOO-JIN LEE: Great. I'd like to

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thank Natasha, Eric, and Aaron today. And all

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of you, for this rich and robust discussion.

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This is clearly a timely and critical set of

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issues. And there's been such great

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engagement. For those of you who can, please

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join us for our post-event discussion. The

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link is in the chat. We will be taking a break

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for the month of August, and we'll begin our

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third year of ELSI Friday Forum on

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September 9th, which will be... which will be

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the first of the academic year. Next year's

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series will have a special focus on global

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genetics, through which we will highlight

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international perspectives. More information

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on the series will be forthcoming, so please

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mark your calendar for September 9th, and we

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look forward to seeing you then. Also, you can

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certainly subscribe to our newsletter on

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eLSIhub.org if you want information about this

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Forum, as well as other resources. Also, you

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will receive a post-event survey. I encourage

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you to complete this, as our organizing

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committee takes your comments and suggestions

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very seriously. It has informed us on how to

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improve the Forum and bring new topics and

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speakers to you, so please, please, DO fill

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that out.

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I hope you all have a great weekend.