

Legal and Policy Challenges to Privacy in the Post-Genomic and Post-Dobbs Era

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Legal and Policy Challenges to Privacy in the Post-Genomic Era

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Disclosures

- I was a member of the Genetic Genealogy Working Group organized by Maryland Sen. Charles Sydnor III and Maryland Del. Emily Shetty.
- My work on IGG has been supported by a Greenwall Foundation Faculty Scholars grant.



POLICY / PRIVACY / TECH

NJ police used baby DNA to investigate crimes, lawsuit claims

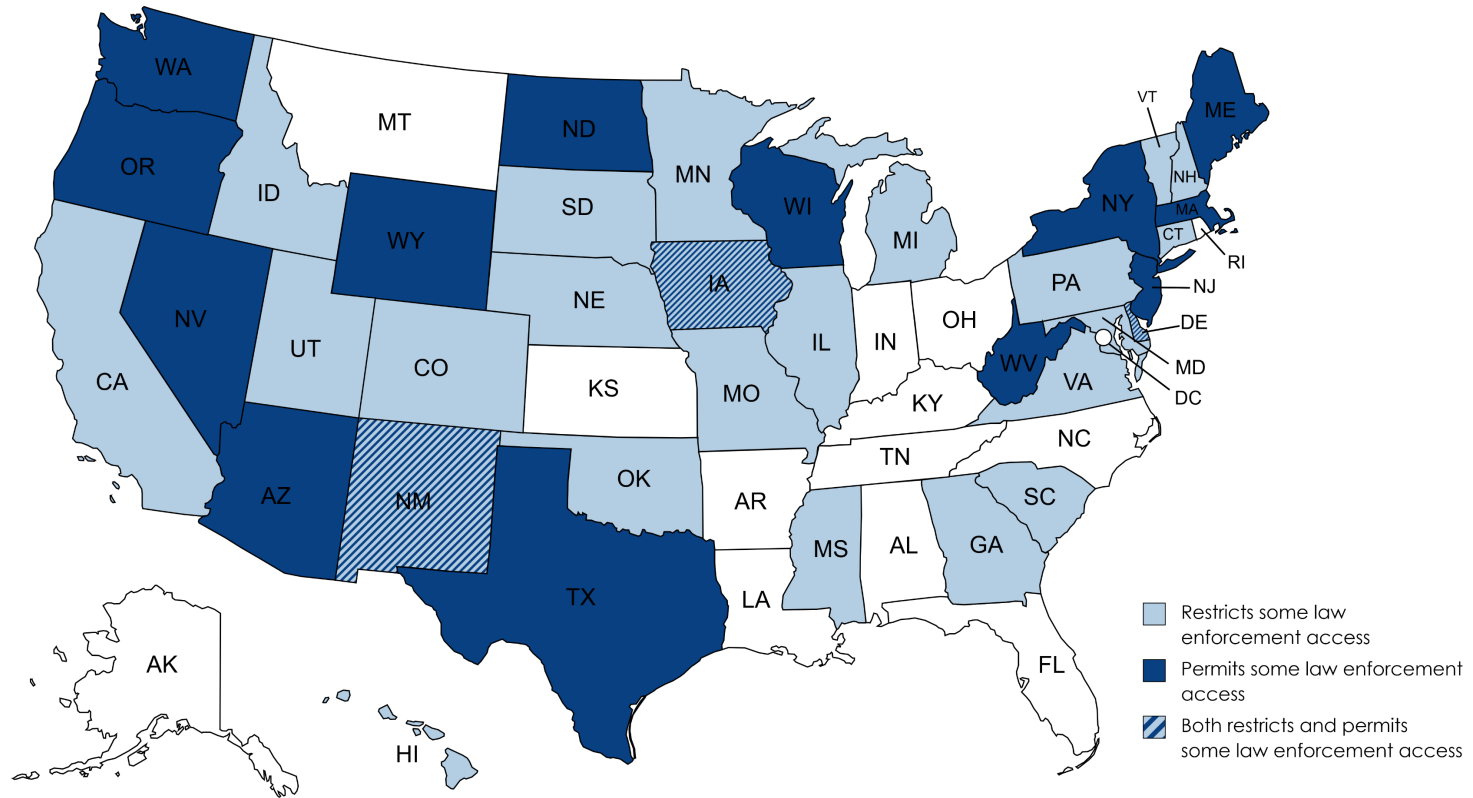


CBS13 Investigates: CA Still Storing Newborn DNA Without Consent. Golden State Killer Case Raising New Concerns

<https://www.sciencemag.org/news/2018/10/we-will-find-you-dna-search-used-nab-golden-state-killer-can-home-about-60-white>



Mapping state policies





LAWRENCE J. HOGAN, JR., Governor

Ch. 681

Chapter 681

(House Bill 240)

AN ACT concerning

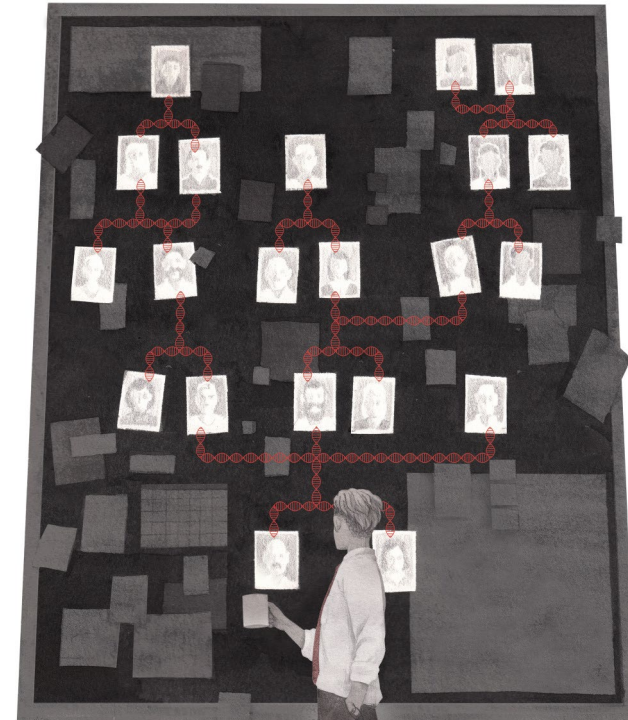
**Criminal Procedure – Forensic Genetic Genealogical DNA Analysis, Searching,
Regulation, and Oversight**

FOR the purpose of establishing that a certain forensic genetic genealogical DNA analysis and search may not be initiated without certifying certain information before a court and obtaining a certain authorization; requiring a court to authorize the initiation of a certain forensic genetic genealogical DNA analysis and search if certain information is certified before the court; prohibiting certain biological samples subjected to certain forensic genetic genealogical profile analysis to be used to determine certain information about a certain donor; providing that a certain forensic genetic genealogical DNA analysis and search shall only be conducted under certain circumstances; requiring that the laboratory conducting certain single–nucleotide polymorphisms or other sequencing–based testing has a certain license; requiring certain informed consent in writing to be obtained from a certain third party under certain circumstances; requiring that a person obtaining a certain informed consent have certain training within a certain period of time; requiring that



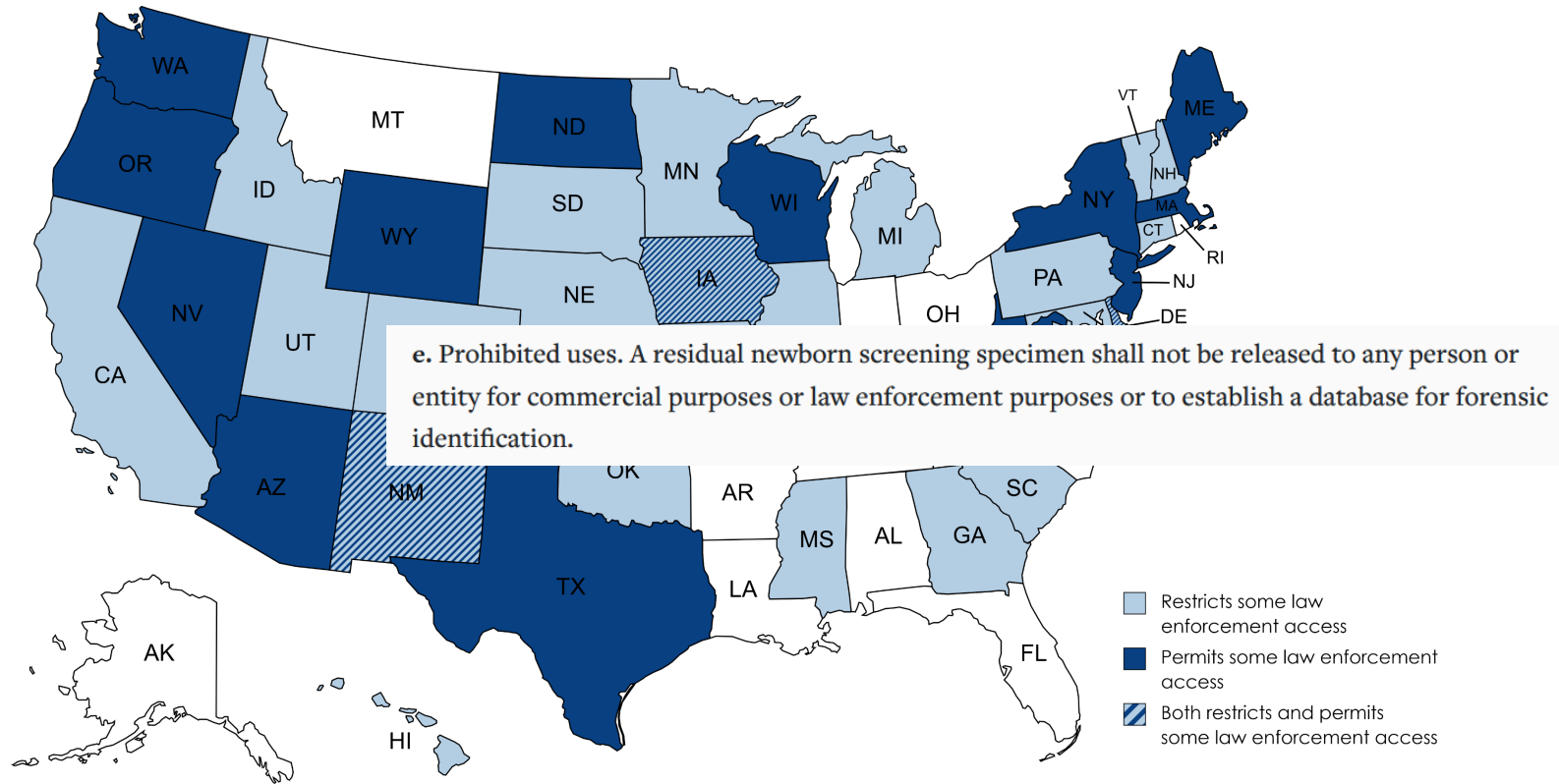
HB 240: Six critical features

- Ex ante judicial supervision
- Acknowledgment and consent from site users regarding law enforcement use
- Robust protections for non-suspect third parties
- Defense and post-conviction access
- Real consequences for violations
- Annual public reporting and review





Mapping state policies



JUNE 2023 ELSI FRIDAY FORUM
GENETIC PRIVACY IN THE POST-DOBBS ERA:
PRENATAL GENE THERAPY

ALTA CHARO

PROFESSOR EMERITA OF LAW & BIOETHICS, UNIVERSITY OF WISCONSIN
PRINCIPAL, ALTA CHARO CONSULTING, LLC

BIAS AND CONFLICT:

CO-ORGANIZER OF WORKSHOP ON PRENATAL GENE THERAPY, NOW WORKING TOWARD
DEVELOPING ETHICS CONSENSUS STATEMENT

CONSULTANT ON RESEARCH TRIAL ETHICS/DESIGN (J&J, VERTEX, EGENESIS), ON FETAL
TISSUE USE IN RESEARCH (BIO, PLANNED PARENTHOOD), ON ASSISTED REPRODUCTION
(CONCEPTION, GAMETO), AND OTHER PAID CONSULTANCIES UNRELATED TO THE TOPICS
DISCUSSED TODAY.

WHY DO IN UTERO GENE THERAPY AND GENOME EDITING?

Fetal immune system is uniquely wired for tolerance

- lack of immune memory means re-dosing w vector possible

Fetal stem cells could be more accessible.

- Access and edit hematopoietic stem cells in the fetal liver before they retire in the bone marrow

Permeability of the blood-brain barrier (BBB) allows agents to access the central nervous system

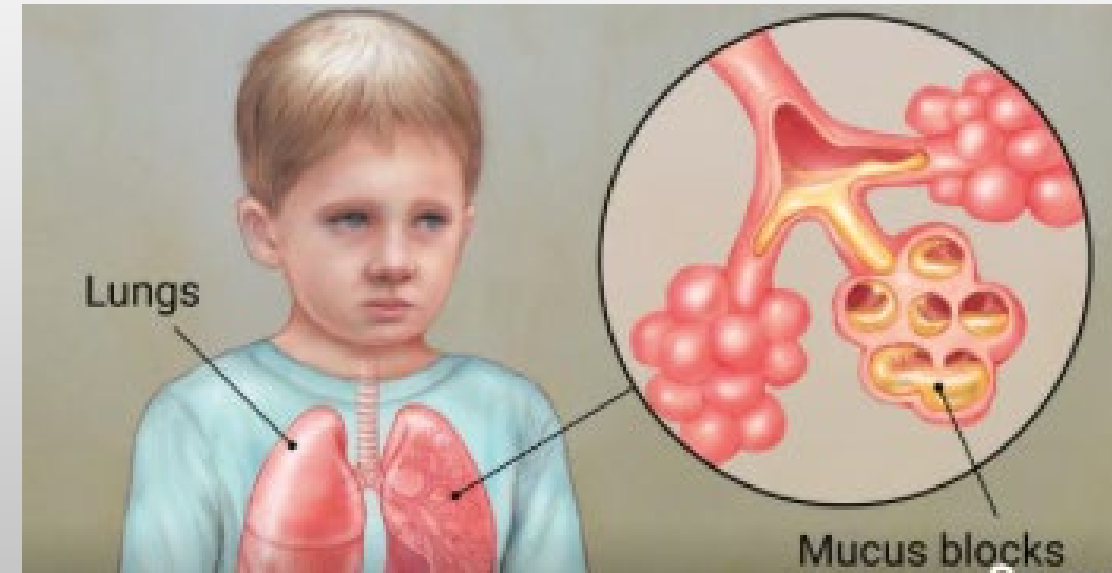
- important for neurological diseases

Size of the fetus allows for lower absolute doses and widespread distribution of the therapeutic agent

- vector manufacturing less of a bottleneck
- substantial economic and medical advantages, primarily by preventing disease before the development of its clinical course.

EXAMPLE: CYSTIC FIBROSIS

- AFFECTS CELLS THAT PRODUCE MUCUS, SWEAT, DIGESTIVE JUICES.
- CAUSES FLUIDS TO BECOME THICK AND STICKY, THEN PLUG UP TUBES, DUCTS, AND PASSAGEWAYS.
- SYSTEMIC EFFECTS CAN BE HARD TO TREAT POSTNATALLY
- DIFFICULT GETTING CORRECTIVE GENES INTO DEEPEST PARTS OF LUNG
- IN UTERO CORRECTIVE GENES CAN REACH INTERSTICES
- BUT – RISKS OF UNINTENDED EFFECTS, INCLUDING ON GAMETES



QUESTIONS

Who is (are) the patient(s)?

How is risk and benefit measured?

How does the availability of abortion affect the calculus?

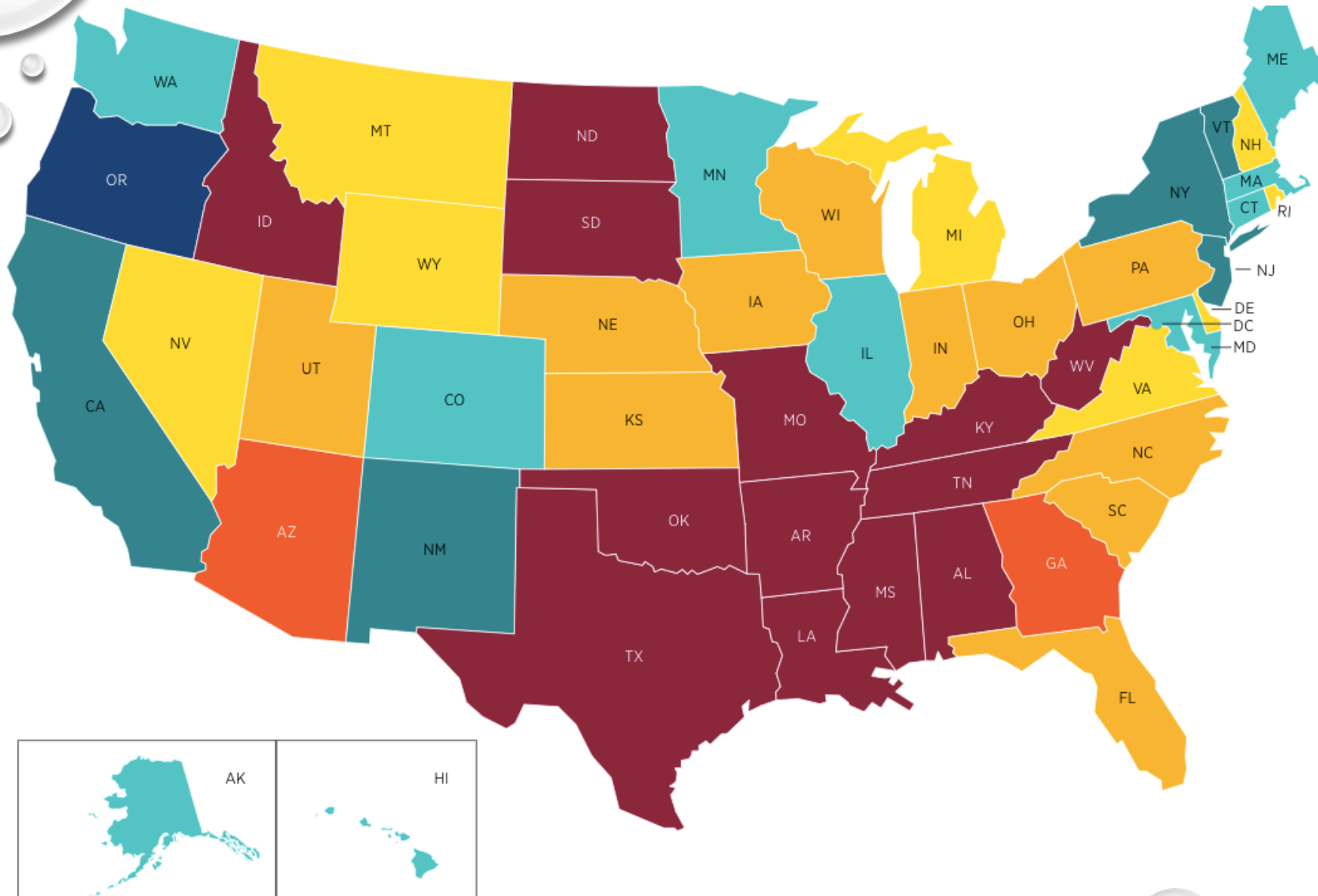
Who gives consent?

What special risks and opportunities are presented by gene therapy and genome editing?

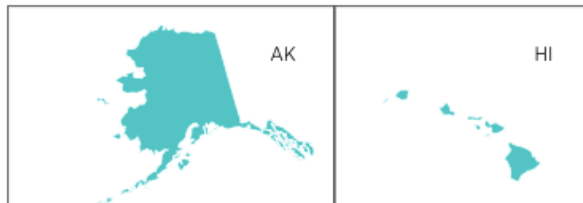
How do NIH and FDA provisions on research with pregnant women apply?



Post-Dobbs Abortion Map



- Most restrictive
- Very restrictive
- Restrictive
- Some restrictions/protections
- Protective
- Very protective
- Most protective



The Allan Guttmacher Institute
10 May 2023

45 CFR PART 46:

CONSENT

- IF PROSPECT OF **DIRECT BENEFIT SOLELY TO THE FETUS,** THEN THE **CONSENT OF THE PREGNANT WOMAN AND OF THE FATHER IS REQUIRED**

- FATHER'S CONSENT NOT NEEDED WHEN DUE TO:
 - **UNAVAILABILITY**
 - INCOMPETENCE
 - TEMPORARY INCAPACITY
 - **PREGNANCY RESULTED FROM RAPE OR INCEST.**

- BY THE WAY, WHO IS THE FATHER?
- THE MALE PROGENITOR OR THE INTENDED REARING PARTNER?
- *HOW WILL THE POST-DOBBS POLITICS OF PATERNAL ROLES IN PREGNANCY MANAGEMENT AND ABORTION AFFECT THIS?*



INFORMATION FOR CONSENT

alternative post-natal therapeutic interventions

possibility that even if successful, there might be a miscarriage, a stillbirth, or a child born with serious health problems.

local standards for management of severely impaired neonates

- roles and authority of local law, hospital policy, neonatologists and parents regarding extraordinary measures

whether abortion is available as an alternative

- in lieu of the intervention
- in the event of a failed intervention
- effect of abortion politics (earlier limits)
 - effect on those w/o prior affected child vs those w/experience

Population Descriptors in Genomic Research: Applying the NASEM Recommendations

July 14, 2023 at 12pm ET/9am PT



Ann Morning, PhD
New York University



Molly Przeworski, PhD
Columbia University



Moderated by
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