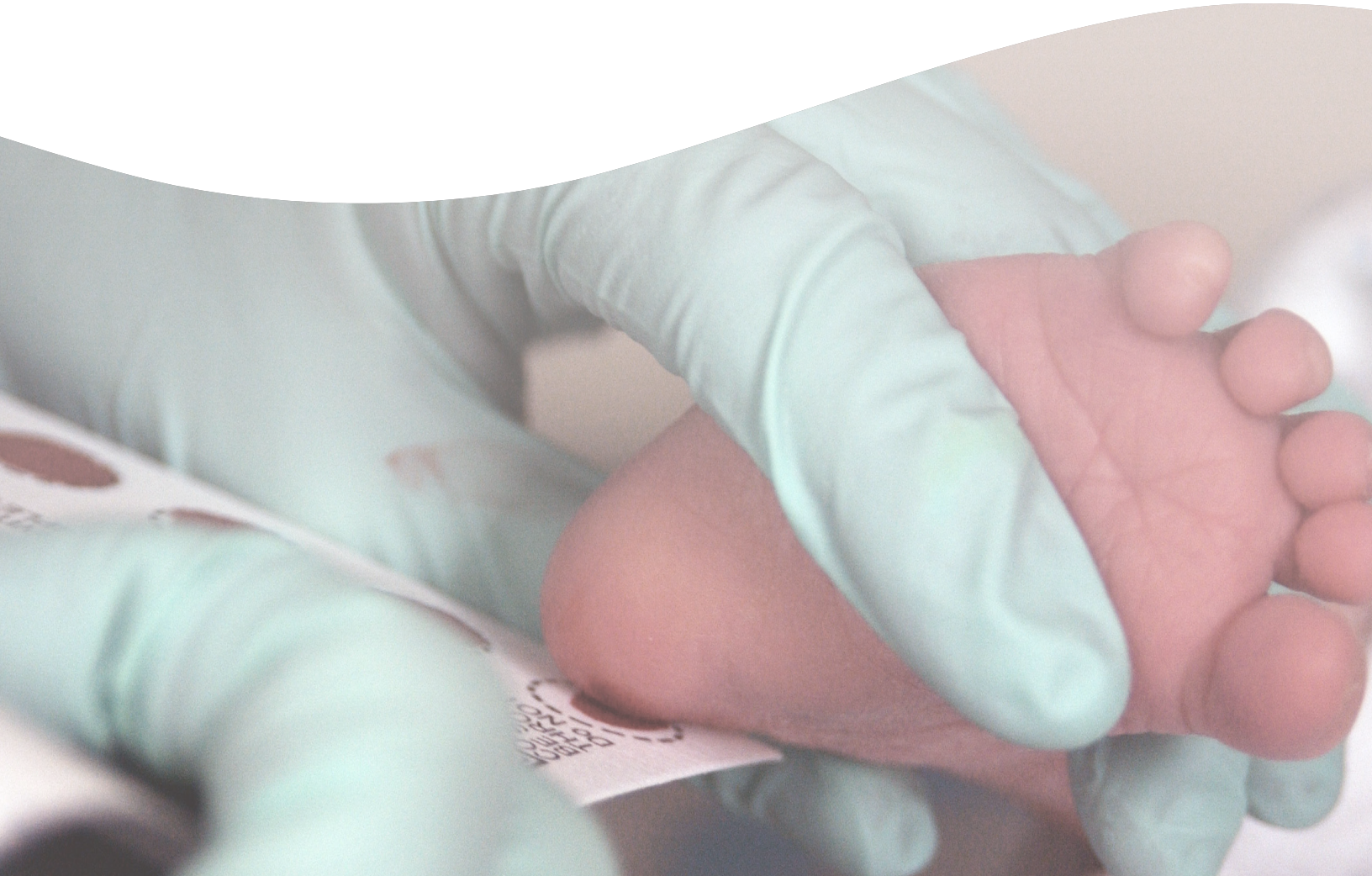
NORD®
National Organization for Rare Disorders

Preserving Public Trust in the U.S. Newborn Screening System

Policy Principles and Recommendations on the Retention and Secondary Use of Residual Dried Blood Spots

FEBRUARY 2025



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Editor's Note:

This paper contains several words or phrases commonly used in the newborn screening and laboratory fields that may be new to the reader. A Glossary of Terms can be found in Section 1 of the Appendix, and these terms are noted in orange when first referenced in the paper. Definitions have been sourced from the Clinical Laboratory Standards Institute's internationally accepted Harmonized Terminology Database and the Health Resources and Services Administration's Newborn Screening Glossary.

01

Executive Summary

Newborn screening is an incredibly successful public health program that saves the lives of thousands of children each year in the United States. It is vital to the rare disease community and the public overall. Leftover newborn screening samples, known as **residual dried blood spots (DBS)**, play a critical role in newborn screening program operations and serve as a valuable resource for public health practice and rare disease research.

However, recent legal challenges and law enforcement actions have drawn attention, sparked controversy, and raised questions about residual DBS retention and secondary use – an issue further complicated by variable policies and requirements across U.S. states and territories. **As newborn screening programs and policymakers across the country work to address these concerns, it is essential to ensure that policy changes do not jeopardize the lifesaving work of these programs.** With health misinformation on the rise and media coverage often omitting details about the original purpose of DBS collection, the newborn screening system must take proactive steps to build trust through policy, transparency, and effective communication.

Between April-May 2024, the National Organization for Rare Disorders (NORD®) conducted interviews with 13 NORD member patient advocacy organizations representing rare disease populations impacted by a condition that is either on the Recommended Uniform Screening Panel (RUSP), currently going through the RUSP nomination process, or expected to begin the RUSP nomination process in the future. Following those interviews, NORD convened representatives from the same patient advocacy organizations for a working group to discuss the overarching interests and concerns of the rare disease community on this topic. With input from this member working group, NORD staff, the Board of Directors' Advocacy Committee, and subject matter experts from across the newborn screening system, NORD has drafted a set of policy principles and recommendations with the goal of fortifying public trust and ensuring continued participation in newborn screening.

This paper:

- Describes the current landscape, challenges, and concerns regarding residual DBS retention and secondary use
- Highlights the interests of the rare disease community
- Presents a set of principles to use as a guide when evaluating current and future DBS policy proposals
- Recommends actions to address the challenges facing newborn screening programs

02

Introduction

Newborn Screening

Newborn blood spot screening (hereafter referred to as **newborn screening**) is among the most effective and longstanding U.S. public health programs. It originated in the 1960s when Dr. Robert Guthrie developed a blood test for phenylketonuria (PKU). This serious metabolic disorder causes brain damage if not detected and treated early in life. Children with PKU appear healthy at birth, but they are born with limited to no function of an enzyme necessary to break down a specific component of proteins. As a result, an amino acid called phenylalanine builds up in the body, causing permanent neurological damage.

Before Dr. Guthrie developed this blood test, children with PKU were not diagnosed until after they had developed irreversible brain damage. The blood test allowed health care providers to detect PKU shortly after birth, enabling earlier treatment and avoiding serious health complications caused by the condition.[1] **Today, nearly 4 million newborns are screened annually in the United States for certain rare conditions that, like PKU, can cause permanent disability or death without early detection and treatment.**[2]

REAL WORLD EXAMPLE: SCID

In the 1970s, many around the world learned of severe combined immunodeficiency (SCID) when David Vetter, affectionately known as "the boy in the bubble," was born. Newborn screening for SCID wasn't available then but is now standard practice in all 50 states because it is a severe but treatable condition if identified early. SCID is one of more than 450 rare types of primary immunodeficiency in which affected infants lack the white blood cells needed to fight infection.

Newborn screening has revealed that SCID is more common than previously thought, impacting 1 in 58,000 births. Additionally, a 2007 study found 94% of babies with SCID who received treatment in the first three-and-a-half months of life survived, compared to under 70% for those who were diagnosed with SCID later in life.

Before newborn screening, this hereditary condition was only screened for after the death of a parent, older sibling, or other close relative. Among children with SCID identified by newborn screening rather than illness or family history, 92.5% survived five years or more after treatment. Without universal newborn screening, SCID diagnosis could return to the days when families endured the loss of a child before being able to access screening for their next baby.

David Vetter photo courtesy of the Immune Deficiency Foundation, primaryimmune.org.

All 50 states, most U.S. territories, and the District of Columbia currently mandate screening for at least 31 serious, rare conditions. Each **jurisdiction** determines the specific conditions screened, with most **newborn screening programs** currently testing for most of the 38 conditions included on the Recommended Uniform Screening Panel (RUSP). **Because babies born with these serious conditions typically appear healthy at birth, screening is critical to ensure affected newborns receive care, treatment, or intervention as early as possible.**

Shortly after birth, typically within 48 hours, a health care provider pricks a newborn's heel and collects several blood spots on a filter paper card. The hospital then sends the **dried blood spots (DBS)** to a public health laboratory where lab staff test the newborn's blood for conditions on the state or territory's **newborn screening panel**. If a screen comes back positive, the health department informs the newborn's health care provider, who notifies the newborn's parents and connects the family to an appropriate specialist for follow-up testing.[1]

The Recommended Uniform Screening Panel (RUSP) is a list of conditions for which the U.S. Secretary of Health and Human Services recommends newborns receive screening. Conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. While states and territories ultimately determine what disorders their newborn screening program will screen for, the RUSP establishes guidelines for states to use when determining which conditions to include on their newborn screening panel.

Laboratories typically do not use all the blood spots on a newborn's filter paper card to run tests for the conditions on a program's newborn screening panel. Leftover samples, known as **residual DBS**, are critical to the functioning of newborn screening programs. **Public health laboratories rely on residual DBS to perform important laboratory activities** such as **quality assurance and improvement (QA/QI)**, **calibrating** laboratory equipment, and **validating** new and existing screening methods.

Residual DBS also provide a valuable resource for public health practitioners and researchers. For example, residual DBS retained by the state of Michigan have been used to study the impacts of environmental toxin exposure during pregnancy on birth outcomes, to research the prevalence of genetic variants related to hereditary hemochromatosis, and to develop or improve screens for several rare disorders.[3]

Controversy, unclear legal and ethical guardrails, and ambiguity around retention and **secondary use** of residual DBS may affect their continued use, and negative public opinion about these practices may ultimately impact the success of newborn screening more broadly. Ethical concerns and litigation regarding consent for residual DBS retention and secondary use have generated media coverage about newborn screening programs and have been a significant obstacle to reauthorizing federal newborn screening support by passing the Newborn Screening Saves Lives Act (NBSSLA). This legislation has not advanced since the previous authorization lapsed in 2019.

Each year, newborn screening identifies approximately 6,700 babies born with rare conditions.[2] **Screening provides these children an opportunity to avoid major medical complications and permanent disability. For some, screening is the difference between life and death.** This is why the rare disease community has a profound interest in the function and sustainability of newborn screening programs, including how programs may be impacted by controversy and ethical issues surrounding residual DBS retention and secondary use. The patient organizations involved in drafting this white paper share a common concern that misinformation and the erosion of public trust could seriously jeopardize the lifesaving work of newborn screening programs and public health research.

REAL WORLD EXAMPLE: CF

Cystic fibrosis (CF) is a progressive genetic disease that impacts the lungs, pancreas, and other organs. For people with CF, early identification allows health care providers to start treatments for CF as early as possible and help parents learn ways to keep their child as healthy as possible. This can help delay or prevent serious, lifelong health problems related to CF. A 2022 study on outcomes for people with CF up to age 10 found that newborn screening for CF in the United States was associated with improved nutritional status, a more rapid increase in lung function, and delayed chronic bacterial infection.

Each year, newborn screening identifies approximately 6,700 babies born with rare conditions.[2]

03

Background

Newborn screening programs in the United States operate at the state or territory level. It is up to each jurisdiction to set policies governing newborn screening program practices, including sample collection, conditions to be screened, consent requirements, and residual DBS retention and secondary use practices. These policies vary significantly, with each jurisdiction deciding how long to retain residual DBS, how residual DBS may be used, and requirements for residual DBS retention and secondary use.

It is of the utmost importance that newborn screening is universal and equitable. While all but one jurisdiction allows parents to opt out of (or refuse) screening on behalf of their child, almost all babies born in the United States are currently screened through state or territory newborn screening programs. Patient organizations across the rare disease community share a major concern that a lack of transparency about residual DBS retention and secondary use and permitting law enforcement access to residual DBS and newborn screening data will erode public trust in newborn screening programs and contribute to screening hesitancy.

Consent for Retention of Residual DBS and Newborn Screening Data

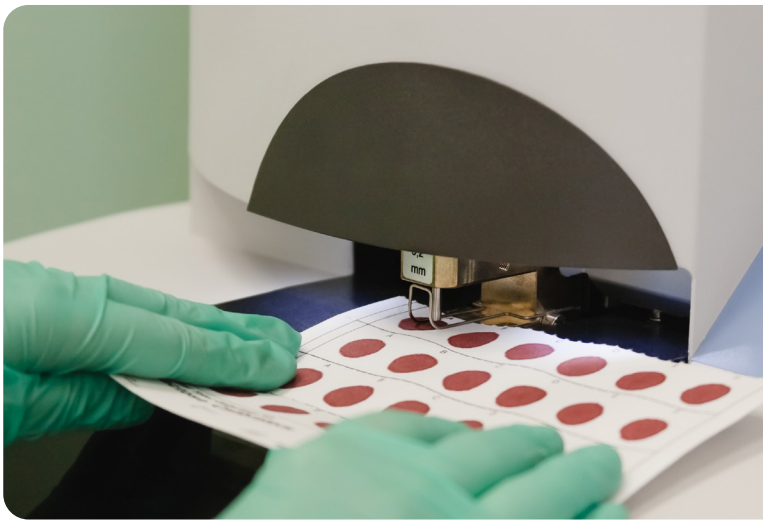
Policies regarding consent for the retention and secondary use of residual DBS for certain activities vary by jurisdiction. For example, Michigan does not require consent from a parent or guardian to retain residual DBS in the state **biobank** following screening but does require consent for residual DBS to be used for research.[4] Texas retains residual DBS for two years before destroying samples unless permitted to retain residual DBS for a longer period of time by the parent or guardian.[5] Minnesota does not require consent for residual DBS retention but allows parents to opt out of retention and requires consent for residual DBS to be used in research.[6] In addition to retaining the physical DBS, most jurisdictions retain the data generated by newborn screening for some period of time, in some cases for more than 20 years.

Secondary Use of Residual DBS for Public Health Practice and Research

Residual DBS are a valuable resource for both public health practice and biomedical and public health research. While the use of residual DBS for both public health practice and research activities may appear to be similar, each has a distinct purpose and the rules, requirements, and ethical principles governing each vary.

Public health practice involves the application of proven methods to monitor the health of a community, investigate unusual occurrences of diseases or other conditions, and implement preventive control measures based on public health sciences.[22] Public health practice activities primarily seek to benefit the participating community. Research, however, involves testing new treatments or strategies that are not yet known to be efficacious, and the benefit often goes beyond the participating community.[22]

Some secondary uses of residual DBS fall neatly into the public health practice or research category, but some uses, such as new test development, fall into a more complicated gray area. **Policymakers must understand the intent and purpose of specific activities when making decisions that could impact requirements regarding the secondary use of residual DBS.**



Laboratories use residual DBS to conduct essential activities critical to properly functioning newborn screening programs. **These include:**

- Laboratory quality control, quality assurance, and improvement
- Calibrating equipment
- Evaluating equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program
- Validating equipment and screening methods
- Developing, testing, and maintaining a plan to ensure continuity of operations in the event of an emergency
- Assuring competency of testing personnel[7]

These activities are standard practice in evaluating the accuracy of laboratory testing.[8] Most routine laboratory activities do not require residual DBS to leave the state or territory's public health laboratory. However, **given the varied DBS retention practices throughout the United States, smaller jurisdictions and those that do not retain residual DBS for an extensive period following screening may rely on larger jurisdictions and those with more extensive retention periods to perform critical program functions.** These may include requesting de-identified residual DBS from other jurisdictions to perform QA/QI and other important activities, as well as using updated/new screening methods developed by other labs.

De-identified specimen sharing is also particularly relevant when implementing testing for new conditions added to the newborn screening panel. States and territories that allow de-identified residual DBS to be shared with other programs generally have specimen-sharing policies to safeguard the DBS throughout the process.

Once a test is developed and in use, laboratories can also use residual DBS to improve screening methods to make them more accurate and affordable.[7] For example, scientists and advocates have been working to improve the screening test for the metabolic disorder homocystinuria, as it's estimated that the current screening method misses approximately 50% of cases.[11] **When screening fails to identify a child at risk of having a condition on the newborn screening panel and they are diagnosed later in life, retesting the residual DBS can help uncover the reason for the false negative result and inform efforts to improve the screen.**

Residual DBS also provide a unique opportunity for biomedical and public health research. Since nearly all children born in the United States participate in newborn screening, residual DBS repositories can supply a nearly complete representation of the population that cannot be found anywhere else.[7] Residual DBS can be used on their own or integrated with existing public health data as a resource for genetic and infectious disease epidemiology, as well as for research on pharmacological exposures, birth defects, developmental disability, environmental toxin exposure, and more.[9]

DEVELOPING NEW SCREENS

Access to residual DBS is particularly important for the rare disease community because **DBS play an integral role in developing new screening methods for rare conditions.** To develop tests capable of identifying newborns at high risk for having a condition at the population level, laboratories require access to a pool of samples reflective of the condition of interest's prevalence in the general population.[10] For rare conditions, preserving even a tiny representative pool of samples requires an extensive repository of residual DBS.

Applicable Laws and Policies for Residual DBS Research Use

Just as the structure and operation of newborn screening programs vary by jurisdiction, so do the applicable laws and policies to safeguard residual DBS and newborn screening data during research use. All newborn screening testing in the United States is conducted by laboratories licensed by their respective jurisdiction and must meet Clinical Laboratory Improvement Amendments Act of 1988 (CLIA) requirements.[8] Some laboratories are considered covered entities, and the privacy of individually identifiable health information is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[7]

Additionally, all federally funded research is subject to the ethical requirements of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.[12] While the Common Rule does not require researchers to obtain informed consent to use de-identified residual DBS for research, many states still choose to obtain consent.

Further, many jurisdictions that allow residual DBS use for research require a committee known as an Institutional Review Board (IRB) to review that research. The IRB ensures that the proposed research meets ethical standards and protects the safety and rights of participants. Consent and IRB approval are always required to use identifiable residual DBS for research. See **Section 2 of the Appendix** for a table showing state and territorial residual DBS retention policies. (Please note that these data are self-reported by jurisdictions annually.)

Use of Residual DBS for Forensic Purposes

Residual DBS are sometimes used for forensic purposes. On rare occasions, residual DBS will be the best source of DNA for the identification of a missing or deceased child.[9]

However, in recent years, some law enforcement agencies have accessed residual DBS for investigatory purposes. The New Jersey Office of the Public Defender filed a lawsuit in 2022 after discovering that state law enforcement had accessed the residual DBS of a 9-year-old to tie their client, the child's father, to a crime.[13]

It is currently unclear how widespread this practice might be in other states, territories, and the United States more broadly. A 2022 Texas Law Review Article surveyed state laws related to law enforcement access to residual DBS and derived data. The review found that more than a quarter of U.S. states have no discernible policy regarding law enforcement access, while a third of states have policies that permit law enforcement access.[14]

Among those states with a law regarding law enforcement access, some laws are general genetic privacy statutes, while others apply specifically to newborn screening. As of the article's publication, no states had a policy that bars law enforcement access to both residual DBS and the derived data.[14] The map in **Section 3 of the Appendix** categorizes state policies according to law enforcement access (information as of 2022).

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Legal Issues

As mentioned, the retention and secondary use of residual dried blood spots has been at the center of lawsuits in several states. These legal challenges fall primarily into three categories:

Challenges Under State Privacy Laws

Parents in Minnesota and Michigan have challenged the newborn screening program's retention and secondary use of residual DBS under state laws governing genetic privacy and informed consent requirements.[15,16] Plaintiffs argue that the newborn screening program violated state law by using blood spots for purposes other than newborn screening or retaining residual blood spots without obtaining adequate permission from the newborn's parent or guardian.

Challenges Under the Fourth Amendment

A settled case in Texas and ongoing litigation in Michigan and New Jersey allege that the newborn screening program's retention and secondary use of residual DBS violates the plaintiffs' Fourth Amendment right to be secure in their persons and free from unreasonable searches and seizures.[16,17,18] They argue the initial drawing and collection of blood from a newborn constitutes a search and seizure under the Fourth Amendment and that the retention of residual DBS following initial screening is a continued seizure. While the plaintiffs do not challenge the initial collection of blood for newborn screening, they argue the state no longer has a justification for the continued seizure (i.e., retention) of residual DBS once screening is complete.

Challenges Under the Fourteenth Amendment

The Texas, Michigan, and New Jersey cases also allege that the newborn screening program's retention and secondary use of residual DBS violates the Due Process Clause of the Fourteenth Amendment. Specifically, the plaintiffs allege the newborn screening program's residual DBS practices violate the plaintiff parents' fundamental due process right to direct the care, custody, and control of their children without undue state interference. They argue that retaining residual DBS interferes with their ability to make medical decisions for their children.

See **Section 4 of the Appendix** for additional information about the settled cases in Texas and Minnesota and ongoing litigation in Michigan and New Jersey.

05

Policy Principles & Recommendations

The policy principles and recommendations included in this white paper were informed by interviews conducted with 13 NORD member patient advocacy organizations that represent rare disease populations either impacted by conditions listed on the Recommended Uniform Screening Panel (RUSP), currently going through the RUSP nomination process, or expected to begin the RUSP nomination process in the future.

Following the interviews, NORD convened representatives from the same patient advocacy organizations for a working group to share interview findings and discuss the interests of the rare disease community. Based on these conversations and input from NORD staff, members of the Board of Directors' Advocacy Committee, and subject matter experts from across the newborn screening system, NORD developed the following policy principles and recommendations.

Policy Principles

It is critical that newborn screening programs continue to meet their goals and that newborns with rare conditions receive the treatment and care they need without delay. While the privacy concerns regarding the retention and secondary use of residual DBS are valid, **it is important to ensure that any policy developed to address these concerns does not negatively affect the ability of newborn screening programs to continue their lifesaving work.** The following four principles should be used to help guide support or opposition to current and future residual DBS policy proposals.

1. Newborn screening programs should be good stewards of residual DBS and newborn screening data.

- Programs should establish and preserve robust privacy and confidentiality protections to safeguard residual DBS and newborn screening data.
- Programs should have specimen-sharing policies and material transfer agreements to protect shared information (e.g., purpose specification, prohibition on reidentification).
- Programs should never permit law enforcement access to residual DBS and newborn screening data.

2. Newborn screening programs should continue or take action to preserve autonomy and choice in decision-making about residual DBS retention and secondary use.

- Programs should prioritize parent/guardian education and transparency regarding the purposes and possibilities of residual DBS retention and secondary use.
- Programs should continue to obtain consent for any research use of identifiable residual DBS or newborn screening data.
- Parents/guardians should be allowed to choose whether their child's residual DBS will be used for purposes other than newborn screening and critical program activities.
- Parents/guardians (or the individual once of legal age) should have the option to obtain their child's residual DBS for retention and research use before the sample is destroyed.

3. Secondary use of residual DBS should advance public health and the optimal functioning of newborn screening programs.

- Policies should not jeopardize the universality of newborn screening and should support equity within the newborn screening system.
- Residual DBS policies should not interfere with the newborn screening program's ability to conduct critical program activities.
- Residual DBS and newborn screening data should only be used for purposes directly related to newborn screening activities or public health research.

4. Decisions and policies regarding residual DBS retention and secondary use should be transparent and accessible to the public.

- Newborn screening programs should be transparent with individuals and the public about potential secondary uses of residual DBS.
- Programs should clearly outline applicable requirements for the secondary use of residual DBS, such as de-identification, consent requirements, IRB review, etc.
- Programs should publish information about research projects that use residual DBS on a publicly accessible website.
- Programs should publish specimen-sharing policies, material transfer agreements, etc., on a publicly accessible website.
- Policymakers should ensure newborn screening programs have a mechanism for the public to provide regular input on newborn screening program policies.

Recommendations

This paper recommends a four-part approach to evaluate and address the current challenges facing newborn screening programs:

1. Support Newborn Screening Programs Through Policy Change

States and territories should take swift policy action to bar law enforcement access to residual DBS and newborn screening data.

Allowing law enforcement to access residual DBS and newborn screening data does not serve to advance any public health interest and undermines public trust in newborn screening programs. The consensus among the patient organizations that participated in developing this white paper is that the potential harm of this practice far outweighs any benefits. As outlined earlier, state and territorial policies governing law enforcement access to residual DBS vary widely. No jurisdiction was found to have an adequate policy in place barring law enforcement access to both residual DBS and newborn screening data. States and territories should move to close any loophole that allows law enforcement to access these resources.

Congress should reauthorize and provide appropriations for federal newborn screening programs.

Congress enacted the Newborn Screening Saves Lives Act (NBSSLA) in 2008 to support newborn screening efforts by providing grants and establishing federal programs to improve screening and expand public education. The bill also created the Advisory Committee on Heritable Disorders in

Newborns and Children to provide recommendations and advice to the Secretary of Health and Human Services about newborn screening and how to improve the newborn screening system. Congress reauthorized the NBSSLA in 2014 but failed to reauthorize the law by its next deadline in 2019.

Newborn screening programs rely on funding opportunities, services, and support from the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and other federal programs. Federal support helps states access information, expertise, and guidance to improve and expand their newborn screening programs.

The 119th Congress should reauthorize and provide appropriations for:

- HRSA and CDC grants to help states expand and improve their newborn screening programs; educate the public, parents/guardians, and health care providers; maintain a national technical assistance center; and improve follow-up care for newborns impacted by a condition detected through newborn screening.
- CDC initiatives that support newborn screening, including the CDC Newborn Screening Quality Assurance Program.
- The NIH Hunter Kelly Newborn Screening program, which funds research to identify new treatments for newborn screening conditions and develop new screening technology.
- The Advisory Committee on Heritable Disorders in Newborns and Children.

2. Better Understand Public Perception

Congress should provide appropriations for HRSA to conduct a national survey about newborn screening attitudes and behaviors.

Lawsuits threatening the effective and lifesaving operation of newborn screening programs and related negative media coverage pose serious concerns for these programs' reputation and long-term success. Meanwhile, little information is available about public understanding of newborn screening programs, program practices, and residual DBS retention and secondary use. Additionally, while some states track the number of opt-outs to newborn screening and provide this information to a centralized national repository, little is known about the factors contributing to newborn screening hesitancy.

A national survey on attitudes about newborn screening would help to understand the impact that legal challenges and media coverage have had on public opinion and inform the most effective approach to strengthen and, if necessary, rebuild public trust in newborn screening programs. More data about the factors influencing parents' and guardians' perception of newborn screening could also help provide insights into the reasons for screening hesitancy, identify populations where hesitancy is more prevalent, and inform the development of additional educational materials.

HRSA has previously sponsored similar public opinion surveys, including those on organ donation attitudes and practices, in 2005, 2012, and 2019. These surveys have provided the Healthcare Systems Bureau, the Division of Transplantation, and the organ donation community with timely and reliable data to understand current, changing, and trending public opinion and attitudes about organ donation.

3. Increase Public Awareness and Education

Newborn screening programs and health systems should work with federal and community-based partners to initiate or expand public awareness campaigns.

Newborn screening saves lives, and those familiar with its purpose and impact understand the value of these programs. However, despite the universality of screening, many remain unaware that newborn screening takes place and are unfamiliar with its critical purpose. Newborn screening programs and health systems should initiate or strengthen public awareness campaigns that convey why newborn screening is important, how it is conducted, and the potential consequences of forgoing screening. Because the most effective approach to public health messaging will differ across communities, newborn screening programs and health systems should consider partnering with local health departments, community-based organizations, and/or trusted community leaders to ensure messaging and information are culturally relevant, responsive, and accessible to the intended audience. Engaging local families to share stories of how newborn screening impacted their lives may also be beneficial. Public awareness campaigns can also use existing resources like Baby's First Test's Newborn Screening Awareness Toolkit to develop and share information about newborn screening.

Newborn screening programs and health systems should include language in educational materials emphasizing the importance of residual DBS retention to newborn screening programs.

A primary question asked by those with ethical concerns about residual DBS retention and secondary use is why newborn screening programs must keep these samples after screening is completed. This paper outlines the many reasons why retaining residual DBS is vital not only for public health and rare disease research, but also for the continued success and operation of newborn screening programs.

Furthermore, evidence suggests that education about newborn screening and residual DBS retention and secondary use during the prenatal period can impact perception of newborn screening. A study of 664 pregnant women across three states found that mothers educated about newborn screening and residual DBS retention and secondary use during the prenatal period were more supportive of the newborn screening program, more satisfied with the information they received about both newborn screening and DBS, and less concerned about DBS retention and secondary use when compared with women who did not receive this information during pregnancy.[19]

Educational materials should emphasize the importance of residual DBS retention to the continuation of newborn screening programs and should illustrate the direct connection between residual DBS retention and lives saved by newborn screening.

A 2016 study found that mothers educated about newborn screening and residual DBS retention and secondary use during the prenatal period were more supportive of the newborn screening program.[19]

4. Increase Transparency through Effective Communication

States and territories should increase the visibility of residual DBS retention and secondary use policies to maintain and fortify trust in newborn screening programs.

States and territories may unintentionally make retaining residual DBS seem nefarious by failing to prominently feature residual DBS retention and secondary use policies and information on program websites and educational materials. Jurisdictions can increase policy transparency and understanding by visibly highlighting information, such as:

- Length of residual DBS retention periods
- Potential uses of residual DBS
- Specimen-sharing policies
- Protections to safeguard individual privacy
- Consent processes and forms, if applicable
- Opt-out options, if available
- Whom to contact for more information

States and territories that permit residual DBS use for research should clearly define public health research.

By clearly defining public health research, states can provide the public with reasonable expectations for how residual DBS might be used. Texas, for example, defines a public health purpose as "a purpose that relates to cancer, a birth defect, an infectious disease, a chronic disease, an environmental exposure, or newborn screening."[22] Another helpful strategy is for states to publish an annual list of research approved to use residual DBS retained in the state's repository, as Michigan does, to provide the public with examples of the types of research to which residual DBS are contributing.

06

Conclusion

Newborn screening is an incredibly successful public health program that saves the lives of thousands of children impacted by rare conditions in the United States every year. However, recent legal challenges and law enforcement actions pose a serious threat to states' and territories' ability to retain residual dried blood spots, which are critical to the functioning of newborn screening programs and are extremely valuable to rare disease and public health research.

Trust is a fundamental component of any public health program; newborn screening is no exception. With health misinformation on the rise and negative media coverage often omitting details about the original purpose of dried blood spot collection, newborn screening programs must address the public's concerns and take proactive steps to build trust through **policy change, transparency, and effective communication.**

07

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Appendix

Section 1: Glossary of Terms

Biobank or Biorepository: A collection of biological samples and related data that is stored for future research.

Calibration: Comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy in order to detect any variation from the required performance specification.

Confirmatory/Diagnostic Test: A test to prove or disprove the presence of a specific disease, group of diseases, or phenotypic difference suspected based on screening test results.

Dried Blood Spot (DBS): A specimen collected for laboratory testing (in this case, newborn blood spot screening) using specified filter paper on which printed circles indicate the area to be filled with whole blood and air-dried for transport or retention.

False Negative: A screen-negative result in an affected newborn.

False Positive: A screen-positive result in an unaffected newborn.

Jurisdiction: Refers to any area within geopolitical boundaries such as a city, a county, multiple counties, a state, a region, or nation, within which a governmental agency has legal authority to perform a clearly defined function. For the purposes of this publication: a state, territory, or the District of Columbia.

Legally Responsible Party: The parent or guardian of a newborn from whom a dried blood spot sample was collected for newborn screening or the person who has provided a dried blood spot sample once they are of legal age.

Newborn Blood Spot Screening: The process of checking babies to identify those who might have certain serious health conditions that can benefit from early treatment or intervention. Screening consists of collecting blood onto a specimen collection device (filter paper specified for newborn screening), testing defined analytes by approved laboratory methods, and reporting results as appropriate.

Newborn Screening Program: A public health program, which is one part of a greater newborn screening system, that operates to reduce morbidity and mortality in newborns with congenital diseases through early detection and intervention. A newborn screening program consists of the jurisdiction's health service components, including policies and regulations, planning and audits, specimen collection and transport, laboratory testing, short- and long-term follow-up, and education.

Newborn Screening System: A collaboration of newborn screening stakeholders, including public and private agencies, organizations, families, policymakers, health care providers, and other caregivers, working together to ensure that all newborns have access to newborn screening and that babies found affected can access appropriate care and optimize health outcomes.

Newborn Screening Panel: A list of conditions for which newborns receive screening at or shortly after birth. The list of conditions on a newborn screening panel varies across U.S. states and territories.

Recommended Uniform Screening Panel (RUSP): The list of conditions for which the U.S. Secretary of Health and Human Services recommends newborns receive screening.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Screening Test: The systematic application of determinations (i.e., measurement procedures, physiological evaluations, or assessments) among a defined population (e.g., newborns) to detect individuals at sufficient risk for a specific disease, group of diseases, or phenotypic difference to merit additional investigation or guide preventive action. Screening tests are not diagnostic.

Screen Positive: A final, reportable result for a disease, group of diseases, or phenotypic difference, based on the newborn screening result(s) and laboratory screening algorithm, indicating that the risk for that disease, group of diseases, or phenotypic difference is higher, and that additional follow-up is needed. A positive screening result is not diagnostic.

Screen Negative: A final, reportable result for a disease, group of diseases, or phenotypic difference, based on the newborn screening result(s) and laboratory screening algorithm, indicating that the risk for that disease, group of diseases, or phenotypic difference is low and that no additional newborn screening follow-up is needed.

Secondary Use: Use of residual dried blood spots for purposes other than the initial and subsequent newborn screening tests.

Quality Control (QC): The set of procedures designed to monitor the test method and the results to ensure appropriate test system performance.

Quality Assurance (QA): A comprehensive set of policies, procedures, and practices used to monitor the laboratory's entire testing process and ensure that the testing site's results are reliable. Part of quality management is focused on providing confidence that quality requirements will be fulfilled.

Quality Improvement (QI): A framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for individuals with rare diseases, healthcare systems, and organizations.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Definitions were obtained from the Health Resources and Services Administration's Newborn Screening Glossary and the Clinical and Laboratory Standards Institute's Harmonized Terminology Database.

Section 2: DBS Retention and Secondary Use Policies by Jurisdiction

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
AK	3 years	16-20/20+	For reference purposes To match babies/ensure all were screened	N/A	None	N/A		Alaska Policy
AL	3 months	20+/20+	QA/QC Repeat testing	N/A	None	N/A		Policy not found on state website or in statute/ regulations
AR	1 year	20+/20+	QA/QC Research purposes	Consent required	Have a memorandum of agreement (MOA) with the state Center for Birth Defects Research group to release residual DBS with parental consent	N/A		Policy not found on state website or in statute/ regulations
AS	No information found	No information found	No information found	N/A	None	N/A		Policy not found on American Samoa website or in statute/ regulations
AZ	3 months*	20+/20+	QA/QC	N/A	None	N/A	*Specimens of interest or positive samples may be kept without demographic information for QA/QC and training purposes.	Arizona Policy
CA	Indefinitely	20+/20+	QA/QC	Consent required for identifiable DBS Aggregate and de-identified data may be shared without consent	Policy for quality assurance with private entities to develop tests Policy for quality assurance with other NBS program Policy for research with appropriate approval Identified specimens must be consented for research Aggregate and de-identified data may be shared without consent	Parents or the patient may request the bloodspot be destroyed.		California Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
CO	6 months	16-20/ 16-20	None	N/A	None	N/A		Colorado Policy
CT	3 years (2+ current)	3-5/3-5	QA/QC	N/A	None	N/A		Connecticut Policy
DC	1 year	No information found	No information found	N/A	None	N/A		Policy not found on state website or in statute/ regulations
DE	90 days	20+/20+	None	N/A	None	Parents may elect not to participate in DBS storage following testing.		Delaware Policy
GA	4 months for normal, 1 year for abnormal	2>/2>	QA/QC Research purposes	Consent required	Policy for research with appropriate approval Policy for quality assurance with other NBS program	Parents may request to have their newborn's DBS destroyed 12 weeks after the completion of testing.		Georgia Policy
GU	1 year	20+/20+	No information found	N/A	None	N/A		Policy not found on Guam website or in statute/ regulations
HI	1 year	6-10/20+	QA/QC	N/A	Policy for quality assurance with other NBS program	N/A		Hawaii Policy
IA	5 years	20+/20+	QA/QC Research purposes	Consent required for research Prohibits commercial, law enforcement, or forensic database use	Policy for research with appropriate approval Policy for quality assurance with other NBS program	If a parent/ guardian does not want their newborn's DBS retained, they can contact the Iowa newborn screening program to have the bloodspot destroyed or returned to them.		Iowa Policy
ID	18 months	16-20/16-20	None	N/A	None	Parents can request the release of their newborn's DBS by filling out a form.		Idaho Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
IL	2-6 months for normal, 6+ years for abnormal	2>/6-10	QA/QC Can be released to a health care provider or designated laboratory for further analysis with parental consent	N/A	None	N/A		Illinois Policy
IN	6 months for all DBS, 3 years with additional consent	20+/20+	Research purposes	Consent required	Policy for research with appropriate approval	If a parent previously gave consent for retention of DBS but now wishes for the DBS to be destroyed, they can request it be destroyed via a form. Parents who did not previously consent for retention but decides they would like their newborn's DBS retained can also request it be retained, as long as the request is made within 6 months of initial testing.		Indiana Policy
KS	30 days for normal, confirmed cases are deidentified and stored indefinitely	20+/20+	QA/QC	N/A	Policy for quality assurance with other NBS program	N/A		Policy not found on state website or in statute/ regulations
KY	2 months	20+/20+	QA/QC	N/A	Policy for quality assurance with other NBS program	N/A		Policy not found on state website or in statute/ regulations
LA	1 year	20+/20+	QA/QC Research purposes	Consent required	Share specimens with CDC for QA/ QC	N/A		Louisiana Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
MA	15 years	11-15/20+	QA/QC Research purposes	Consent required	Policy for quality assurance with other NBS program Policy for research with appropriate approval	Upon written request from all parents or legal guardians of a child, the child's DBS will be destroyed within a reasonable period of time, not to exceed 1 year from the receipt of the written request.		Mass. Policy
MD	25 years	20+/20+	Research purposes	Consent required	Policy for research with appropriate approval	N/A		Maryland Policy
ME	Indefinitely	20+/20+	QA/QC Released only with parental consent	N/A	None	DBS can be destroyed at parent's request.		Maine Policy
MI	Up to 100 years, currently destroyed after 35 years	No information found	QA/QC Research purposes	Consent required	Policy for research with appropriate approval	Parents can request their child's DBS not be used for de-identified research or for their child's DBS to be destroyed. Parents can also request their child's dried bloodspot be released to them for personal use.	Michigan Department of Health and Human Services policy states that the Department will only provide DBS to law enforcement with consent of the individual, a parent, a guardian, or another authorized representative.	Michigan Policy
MN	May be stored indefinitely, current practice is to store for 5-6 years	20+/20+	QA/QC Research purposes	Consent required Acceptable uses without consent detailed in statute 144.125 subdivision 5		Parents can request their child's DBS be destroyed. Parents who consent for DBS use in research can revoke that consent at any time.		Minnesota Policy
MO	5 years	20+/20+	QA/QC Disorder pilot studies and implement-ations De-identified research purposes	Consent not required for anonymous research No research is conducted on DBS that are < 3 months old to give parents who don't want their newborn's DBS used for research time to opt out	Policy for quality assurance with other NBS program Policy for research with appropriate approval Policy for quality assurance with private entities to develop tests	Parents can have their child's DBS returned to them, destroyed, or request the DBS be retained for 5 years but not used for de-identified research purposes.		Missouri Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
MP	No information found	No information found	No information found	N/A	None	N/A		Policy not found on Northern Mariana Islands website or in statute/ regulations
MS	1 year	<2/<2	Test confirmation	NA	None	N/A		Mississippi Policy
MT	1 year for in-range results, indefinitely for out-of-range results	3-5/3-5	QA/QC	N/A	Share specimens with medical consultants if needed	Parents can request their newborn's DBS be destroyed before the time recommended in state rule.		Montana Policy
NC	5 years	3-5/3-5	QA/QC	N/A	Policy for research with appropriate approval	N/A		Policy not found on state website or in statute/ regulations
ND	18 years	20+/20+	QA/QC	N/A	Shared with regional screening lab for QA	Parents can request to have their child's DBS returned to them.		North Dakota Policy
NE	3 months	20+/20+	QA/QC Research purposes	Consent, IRB approval, Chief Medical Officer approval, Newborn Screening Advisory Committee approval all required	May only be shared for research purposes with consent, IRB approval, Chief Medical Officer approval, State Newborn Screening Advisory Committee approval, and written assurance that the baby's confidentiality is preserved.	Baby's doctor can request DBS for additional testing, such as for cytome-galovirus (CMV).		Nebraska Policy
NH	6 months	<2 years/<2 years	Research purposes	Consent required	Policy for research with appropriate approval	DBS can be obtained for purposes other than newborn screening only with the written authorization of a parent or guardian.		New Hampshire Policy

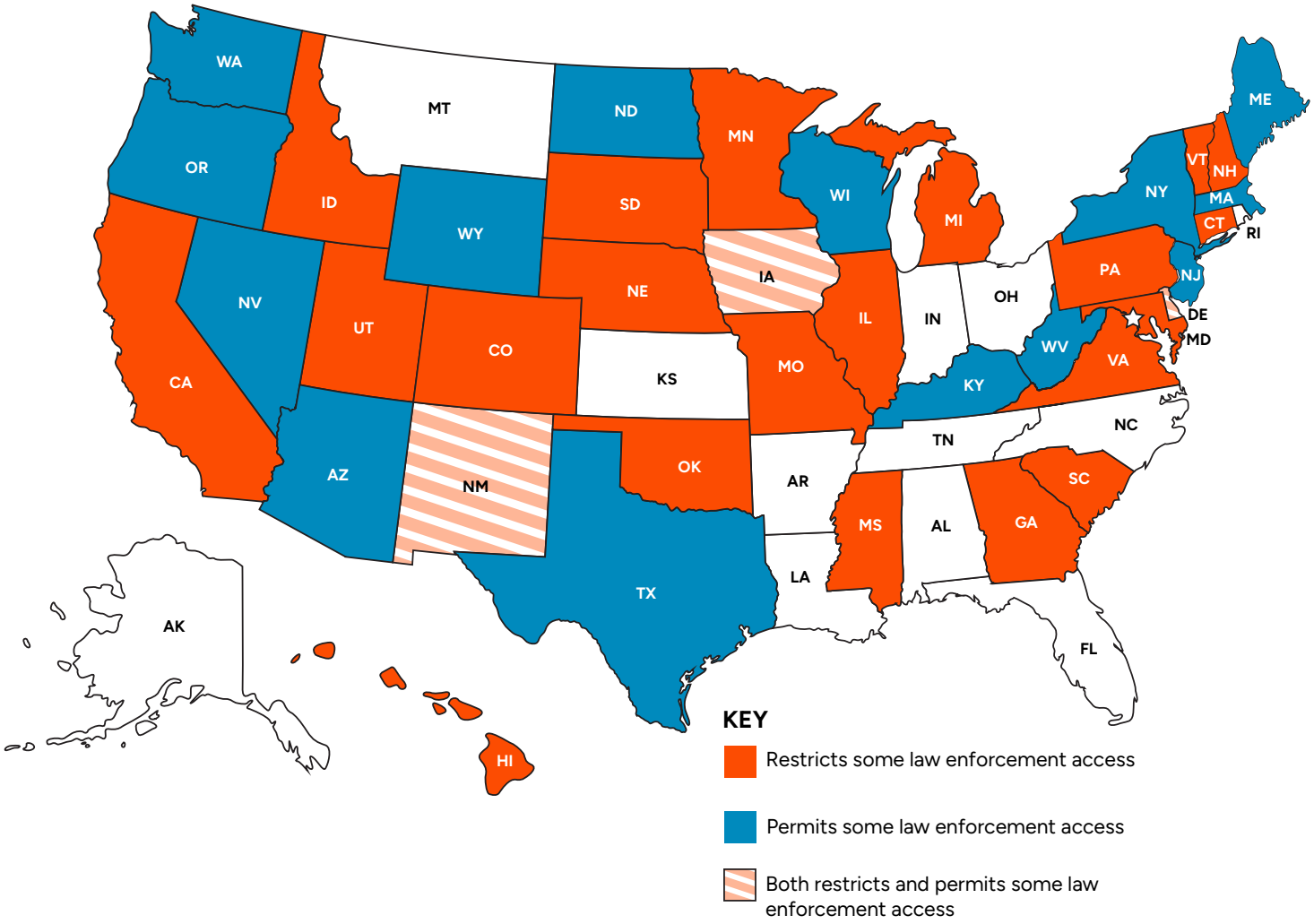
State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
NJ	2 years*	20+/20+	QA/QC Research purposes	Consent required	Policy for quality assurance with other NBS program Policy for research with appropriate approval	A parent or legal guardian can request their child's DBS be destroyed before the end of the 2-year retention period OR for their child's DBS to be retained for longer than the 2-year retention period, up to 10 years.	*Policy effective Nov. 1, 2024	New Jersey Policy
NM	1 year	No information found	QA/QC	N/A	None	Parents or guardians may request DBS in writing during the retention period.		New Mexico Policy
NV	6 months - 1 year	20+/20+	QA/QC	NA	None	N/A		Nevada Policy
NY	Up to 27 years	20+/20+	QA/QC Research purposes Assay development projects Delayed diagnostic investigations Forensic purposes	Specimens that are identifiable must have written consent. Specimens that are deidentified do not need written consent but must go through IRB.	Policy for research with appropriate approval	Parents can request to have their child's DBS destroyed or excluded from research use.		New York Policy
OH	2 years	20+/20+	QA/QC New test implementation and validation	N/A	Policy for research with appropriate approval	N/A		Ohio Policy
OK	Up to 42 days	20+/20+	QA/QC Research purposes	Consent required	None	N/A		Policy not found on state website or in statute/ regulations
OR	18 months	6-10/16-20	QA/QC Research purposes	Consent required	Policy for quality assurance with other NBS program Policy for research with appropriate approval	Parent or guardian can request their child's DBS be returned to them or shipped to a third party.		Oregon Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
PA	1 year	20+/20+	QC Additional testing Forensic purposes	N/A	None	Parent or guardian can request their child's DBS by released to the parent or guardian or destroyed before the 1-year retention period is up.		Pennsylvania Policy
PR	2 years	20+/20+	QA/QC Research purposes	Consent required	Policy for research with appropriate approval	N/A		Puerto Rico Policy
RI	23 years	20+/20+	None	N/A	None	N/A		Policy not found on state website or in statute/ regulations
SC	2 years	6-10/6-10	QA/QC Research purposes	Consent required	Policy for research with appropriate approval	Parents are given the option to have their child's DBS stored but not be used for research, to have their child's DBS destroyed, or to have their child's DBS returned to them 2 years after the date of testing.		South Carolina Policy
SD	1 month	<2 years/<2 years	None	N/A	None	N/A		South Dakota Policy
TN	1 year for normal, indefinitely for confirmed positives	20+/20+	QA/QC	N/A	Policy for quality assurance with other NBS program	N/A		Tennessee Policy
TX	2 years, option for storage for up to 25 years	20+/20+	QA/QC Research purposes	Consent required	Policy for quality assurance with private entities to develop tests Policy for quality assurance with other NBS program Policy for research with appropriate approval	N/A		Texas Policy

State	DBS Retention Period	Data Retention Period in Years (Normal/ Abnormal)	DBS Uses Permitted	Research Consent Policy	Specimen-Sharing Policies	Opt Out?	Notes	Policy On State Website or in Statute/ Regulations
UT	At least 90 days	20+/20+	QA/QC Research purposes Additional testing	Consent required, must go through IRB process and get written parental consent	Policy for research with appropriate approval	Parents can request their child's DBS be destroyed. Parents can request DBS for clinical testing.		Utah Policy
VA	6 months for normal, 10 years for abnormal	20+/20+	QA/QC	N/A	Samples are only shared with the parent/legal guardian upon receipt of a notarized written consent form.	Parent/legal guardian can request their child's DBS be released to them.		Virginia Policy
VI	No information found	No information found	No information found	N/A	None	N/A		Policy not found on U.S. Virgin Islands website or in statute/ regulations
VT	1 year unless parents request otherwise	20+/20+	QA/QC	N/A	None	Parents can send a written request to the Vermont Newborn Screening Program to request their child's DBS be stored longer or destroyed sooner than 1 year.		Vermont Policy
WA	21 years	20+/20+	QA/QC Research purposes Forensic studies Additional testing that is not research-based	Consent required	Policy for research with appropriate approval Policy for quality assurance with other NBS program	Parent/legal guardian can request their child's DBS be destroyed.		Washington Policy
WI	1 year	20+/20+	QA/QC Research purposes	Consent not required	None	Parents can request their newborn's DBS be destroyed.		Wisconsin Policy
WV	3 months	20+/20+	None	N/A	None	N/A		Policy not found on state website or in statute/ regulations
WY	6 months	3-5/3-5	None	N/A	None	N/A		Policy not found on state website or in statute/ regulations

Data obtained from the Association of Public Health Laboratories NewSTEPs State Profiles and the hyperlinked state policies.

Section 3:
Map Showing State Policies on Law Enforcement Access to DBS (as of 2022)



Ram N. America's Hidden National DNA Database. Texas Law Review. July 22, 2022. Accessed July 16, 2024. https://texaslawreview.org/americas-hidden-national-dna-database/.

Section 4: Additional Legal Background

Texas Lawsuit

In 2009, five families sued the Texas Department of Health Services (DHS) for retaining residual DBS and using them for research without obtaining parental consent. The families alleged that the state's retention and secondary use of residual DBS violated their Fourth Amendment right to be free from unnecessary search and seizure and their liberty and privacy rights under the Fourteenth Amendment. In response, Texas amended the newborn screening statute to require DHS to inform parents that the state may retain residual DBS for secondary uses unless the parents object. The families and Texas DHS subsequently agreed to settle the lawsuit out of court. As part of the settlement, Texas DHS was required to destroy all residual DBS taken before May 27, 2009, representing approximately 5 million residual DBS.

Minnesota Lawsuit

Also in 2009, a group of families sued the state of Minnesota, alleging the state violated Minnesota genetic privacy statutes by retaining residual DBS and using them for purposes other than newborn screening. While the Minnesota Department of Health's motion to dismiss was granted in the District Court and upheld in the Court of Appeals, the Minnesota Supreme Court reversed the dismissal in a 2011 decision, ruling that the newborn screening program did not have express authority to retain samples beyond testing and remanded the case to the District Court.

In response to the Minnesota Supreme Court decision, the Minnesota Legislature in 2012 enacted statute Sec. 144.125, which outlines timelines for specimen destruction, requires prenatal education for parents, and allows parents to consent their child's residual DBS for long-term retention and use. The lawsuit was settled in 2013, and as part of the settlement, the Minnesota Department of Health destroyed almost 1 million residual DBS obtained before Nov. 16, 2011.

Michigan Lawsuit

In 2018, nine families sued the Michigan Department of Health and Human Services (MDHHS), alleging that MDHHS' collection, retention, and use of their children's residual DBS violated the Fourth and Fourteenth Amendments. The District Court dismissed the plaintiffs' complaint, and upon appeal, the Sixth Circuit affirmed in part and reversed in part. In a July 2019 opinion, the Sixth Circuit upheld the dismissal of the claims regarding the initial collection and screening of residual DBS. The judge concluded that the plaintiffs' claims regarding the retention and secondary use of residual DBS could proceed and remanded the case to the District Court.

In May 2022, the state agreed to destroy approximately 3.4 million residual DBS as part of a partial settlement, but the case continued. In a September 2022 opinion, the District Court ruled that, while the plaintiffs had signed informed consent forms as required in Michigan, MDHHS did not obtain informed consent for the retention and use of the plaintiffs' children's residual DBS because they had not confirmed that the parents understood what they were consenting to. As such, the Court found that MDHHS had violated the plaintiffs' Fourteenth Amendment right to make medical decisions for their children.[6]

Most recently, in July 2023, the District Court issued a second opinion, finding that the retention and secondary use of residual DBS without informed consent also violates the Fourth Amendment. The state has appealed this decision to the Sixth Circuit, and the case is pending as of January 2025.

New Jersey Lawsuit

In July 2022, the New Jersey Office of the Public Defender (OPD) filed a lawsuit related to residual DBS retention and secondary use. The lawsuit alleged that state police had subpoenaed a newborn blood spot sample belonging to a 9-year-old from the state newborn screening program as part of a criminal investigation. The state police then used that blood spot as probable cause to obtain a warrant for a cheek swab from the child's father. Following DNA analysis, the father was found to be a match to the suspect and was criminally charged.

The New Jersey OPD filed the lawsuit to ascertain how widespread the practice of utilizing residual DBS from the newborn screening laboratory is in criminal investigations. A judge ordered the state to share information about police access to residual DBS. State officials disclosed that the New Jersey newborn screening laboratory had received five subpoenas from four state police agencies over approximately five years.

In November 2023, the Virginia-based nonprofit Institute for Justice filed a federal class action lawsuit in New Jersey with two families serving as lead plaintiffs. Like the Michigan case, the New Jersey lawsuit alleges the state violated the plaintiffs' Fourth and Fourteenth Amendment rights to be free from unreasonable searches and seizures and to direct their children's medical care, respectively.

After months of deliberation, the New Jersey Department of Health released an updated residual DBS retention policy in June 2024.[11] Under the new policy, the Department of Health will retain residual DBS for two years unless the parent or guardian opts for a greater or lesser retention period. According to the Department, the state began to destroy residual DBS older than two years on Nov. 1, 2024.

In addition to the New Jersey Department of Health updating the residual DBS retention policy, New Jersey Attorney General Matthew Platkin issued a directive regarding the investigatory use of records and residual DBS maintained by the newborn screening program on June 20, 2024.[12]

Under the new directive, records and residual DBS can only be obtained from the newborn screening program through a court-issued Dyal subpoena for medical records, rather than a grand jury subpoena; a search warrant based on probable cause; or an administrative subpoena issued in a missing-persons or unidentified-body case.[12]

Despite these changes, the plaintiffs have selected to move forward with the case, amending and refiling their complaint on Aug. 2, 2024. As of January 2025, the case is pending at the District Court for the District of New Jersey.