Use, Retention, and Destruction of Newborn Screening Program Dried Blood Spots

Policy: Newborn screening request forms (Initial, IEM-1; Repeat, IEM-1a), which contain five dried blood spots obtained from a newborn and demographic information about the newborn, are submitted to the Newborn Screening (NBS) Laboratory at the New Jersey Department of Health (NJDOH) for testing, as per N.J.S.A. 26:2-110 and -111 and N.J.A.C. 8:18. The NJDOH shall protect the privacy of all newborns and their families and assure that all forms submitted for screening are protected from unauthorized use or access. *See* N.J.S.A. 26:2-111 and N.J.A.C. 8:18-1.13(a).

1. **Background**
    a. NBS request forms comprise two parts: 1) the "top copy," which only contains demographic information, and 2) the "bottom copy" or "kit", which is a carbon copy of the demographic information with the dried blood spots attached.
    b. All NBS request forms shall be kept, as described in this policy, in a manner to preserve confidentiality.
    c. To conduct newborn screening, hole punches are taken out of the dried blood spots on the bottom copy and tested. Not all dried blood spots are punched for initial screening, which leaves residual dried blood spots ("Residual DBS") on the bottom copy.
    d. Residual DBS that remain attached to identifying information are referred to in this policy as "Identified Specimens." Residual DBS that have been detached from identifying information have been "De-Identified" and are referred to as "De-Identified Specimens."

2. **Retention and Destruction:**
    a. Manner of storage. All newborn screening request forms containing Residual DBS will be retained at ambient temperature and humidity by the NBS Program ("Program") at the New Jersey Public Health and Environmental Laboratory ("PHEL") for a period of no more than 14 days after receipt. After this time has passed, the forms will be transferred to storage boxes containing desiccant and stored in the PHEL facility at -15 to -25 °C. The desiccant will be monitored monthly for replacement.

    b. Default 2-Year Retention of Identified Specimens. Unless a parent or legal guardian requests otherwise, *see* Section 2(f)-(g) below, Identified Specimens will be stored for 2 years and then securely destroyed.

    c. Permissible Uses of Stored Residual DBS.
        i. Identified Specimens stored by NJDOH will only be used for further testing or retesting for the benefit of the newborn from whom the Residual DBS were obtained.
        ii. Identified Specimens stored by NJDOH may be De-Identified and then used for:
            1. Routine quality assurance and quality control, such as ensuring that testing equipment is calibrated correctly, to safeguard the reliability of the Program's testing in accordance with the Centers for Medicare and Medicaid Services regulations, as administered through the Clinical Laboratory Improvements Amendments certification process, *see* 42 C.F.R. § 493.1 *et seq.*; or
            2. The development of testing for additional congenital disorders.

    d. Extended Retention of Certain De-Identified Specimens. Where a newborn's blood has screened positive for a disorder, a portion of the Residual DBS may be De-Identified and then retained for up to 10 years for use as positive control and assay development and validation material. If a such a De-Identified Specimen is no longer needed or its viability becomes reduced, it will be securely destroyed.

    e. Extended Retention to Address Testing Problems. Residual DBS that indicate manufacturing problems associated with the blood spot filter paper or those affected by testing reagent problems ("Investigation

Specimens") may be retained until an investigation into the problem is resolved. Following the conclusion of the investigation, all Investigation Specimens will be securely destroyed in accordance with section 2b above.

f. Right to Request Early Destruction of Identified Specimens. Once all initial newborn screening tests have been completed and the resulting screening results have been reported, and upon request of a parent or legal guardian, Identified Specimens may be destroyed at any time (including prior to the expiration the two-year default retention period described in this policy).

   i. To request the destruction of Identified Specimens, the NJDOH's destruction request form (Appendix 1) must be completed and submitted to the Program.
   ii. After destruction under this section, the requestor shall be notified, in writing, of the completion of the process.

g. Right to Request Extended Retention of Identified Specimens. At the request of a parent or legal guardian, Identified Specimens may be retained for longer than the two-year default retention period described in this policy, up to a maximum of ten total years of retention. A parent or legal guardian may request the destruction of Identified Specimens prior to the end of the 10 years, using the same process as described in section 2(f) above.

   i. To request the extended retention of an Identified Specimen, the NJDOH's retention request form (Appendix 2) must be completed and submitted to the Program.

3. **Access:** Access to stored Specimens shall be restricted to NJDOH employees and contractors, or others approved by the NJDOH, as necessary to meet specific programmatic needs. Access is contingent upon compliance with all applicable federal and state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information.

4. **Release:** Once all initial newborn screening tests have been completed and the resulting screening results have been reported, up to two Residual DBS may be released to the following individuals provided that the request is received prior to the end of the applicable retention period. At least one Identified Residual DBS of satisfactory quality must be retained by the Program. No Residual DBS will ever be sold to any third party. Release is permitted to:

   a. A health care provider or clinical laboratory at the written request of the parent or legal guardian. A completed request form (Appendix 3) must be provided to and reviewed by the Program Manager, or designee, before the request will be fulfilled.

   b. A research laboratory as De-Identified Specimens with approval of the NJDOH Institutional Review Board (IRB), approval of the Public Health Laboratory Services (PHLS) Director, and a fully executed Memorandum of Understanding (MOU) with the NJDOH. If the research project requests Residual DBS with identifying information, then parental or guardian consent will also be required.

   c. A person to whom release is mandated by order of a court of competent jurisdiction.

   d. A law enforcement officer consistent with appropriate legal process as required by the Attorney General's binding Law Enforcement Directive (available at https://www.nj.gov/oag/dcj/agguide/directives/ag-Directive-2024-03_Physical-Blood-Samples.pdf).

5. **Notification:** Parents and legal guardians will be notified of the specimen storage, retention/destruction policies, and access requirements through the NJDOH's newborn screening educational information and website, and they will be provided a QR code link to that website at the time of initial bloodspot collection.

Appendix 1 – Specimen Destruction Request Form

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 371
TRENTON, N.J. 08625-0371
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

Newborn Screening Bloodspots Destruction Request Form

I hereby ask the New Jersey Department of Health Newborn Screening (NBS) Laboratory to destroy the bloodspots from my child's newborn screening request form (IEM-1 and/or IEM-1a).

Child's Name: _____

Date of Birth: _____

Sex Assigned at Birth (circle one): Male / Female

Birth Mother's Name: _____

Birth Hospital: _____

Birth City: _____

Current Address: _____

_____

Newborn Screening request form number (if known): _____

I understand that there are numerous critical benefits to my child from allowing the NBS Laboratory to retain bloodspots linked to my child after collection. These benefits include:

- Clarification of false positive or false negative results.
- Use in diagnosis of later onset disorders.
- Testing certain markers only present at birth (for which bloodspots are the only source).
- Use if my child becomes missing (the bloodspots may be the only remaining source).
- Use in helping to determine the cause of an unexplained death of my child (e.g., SIDS).

Understanding these disclaimers, I still wish to destroy bloodspots linked to my child. I understand that these bloodspots will be forever destroyed and not retrievable or available for any use, including uses potentially critical to the health and welfare of my child.

_____	_____	_____
Parent / Legal Guardian (print name)	Parent / Legal Guardian (signature)	Date

The completed form can be submitted online or faxed to 609-530-8373 or emailed to NJNBS.Results@doh.nj.gov.

Appendix 2 – Specimen Extended Retention Request Form

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 371
TRENTON, N.J. 08625-0371
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

Newborn Screening Bloodspots Extended Retention Request Form

I hereby ask the New Jersey Department of Health Newborn Screening (NBS) Laboratory to retain the identified bloodspots from my child's newborn screening request form (IEM-1 and/or IEM-1a) beyond the 2-year retention policy, for an additional 8 years, for a total of 10 years.

Child's Name: _____

Date of Birth: _____

Sex Assigned at Birth (circle one): Male / Female

Birth Mother's Name: _____

Birth Hospital: _____

Birth City: _____

Current Address: _____

_____

Newborn Screening request form number (if known): _____

I understand that, during these additional 8 years, these bloodspots may continue to be used for: (1) routine quality assurance and quality control, and (2) the development of new tests for the detection of additional disorders. I also understand that one or more of these retained bloodspots that are used for purposes of the quality assurance and quality control and development of new tests may be de-identified (i.e., no longer linked to my child).

I understand that these bloodspots will not be:

- Sold to a third party;
- Released to law enforcement without the consent of a parent or legal guardian, except as consistent with the Attorney General's Directive, available [here];
- Released in identified form for human-subjects research, unless express, written informed consent is received from a parent or legal guardian; or
- Released in a de-identified form for any public health research, unless consistent with federal statutes and regulations.

I understand that this consent is revocable, and that I can therefore still request for any bloodspots linked to my child to be destroyed at any time during the 10-year retention period by completing the form available [here]

_____	_____	_____
Parent / Legal Guardian (print name)	Parent / Legal Guardian (signature)	Date

The completed form can be submitted online or faxed to 609-530-8373 or emailed to NJNBS.Results@doh.nj.gov.

All release requests will be handled in accordance with Department policies.

Appendix 3 - Specimen Release Form

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 371
TRENTON, N.J. 08625-0371
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

Newborn Screening Specimen Release Request Form

I hereby authorize the New Jersey Department of Health Newborn Screening (NBS) Laboratory to release a sample of the residual dried blood spot specimen from my child's newborn screening request form to:

_____

_____

_____

_____

Child's Name: _____

Date of Birth: _____

Sex: Male / Female
(circle one)

Birth Mother's Name: _____

Birth Hospital: _____

Birth City: _____

Purpose of release: _____

_____
Parent / Legal Guardian (print)

_____
Parent / Legal Guardian (signature) Date

The completed form can be submitted by fax to 609-530-8373 or emailed to NJNBS.Results@doh.nj.gov.

All release requests will be handled in accordance with Department policies.