

STATE OF ALASKA Division of Public Health Internal Policies & Procedures	SECTION: All	Number:	Page: 1 of 4
	SUBJECT: Newborn Bloodspot Screening: Use of and Retention of Dried Blood Spots		
	Created: 4/5/2016	Revised:	

PURPOSE:

To provide guidance on the use of and retention of Dried Bloodspots (DBS) obtained for screening in the Newborn Bloodspot Screening Program.

POLICY:

The State of Alaska Newborn Bloodspot Screening Advisory Committee provided input for a policy regarding the use of stored DBS. The Alaska Division of Public Health and the Alaska Department of Law reviewed and approved this policy.

Dried Bloodspots - Permitted Uses

Alaska allows for the following uses of DBS obtained for Newborn Bloodspot Screening and stored by the Alaska Newborn Bloodspot Screening Program:

- Storage and retention according to the Department of Health and Social Services policy and retention schedule, as described in ‘Procedures’ below.
- Program management and quality assurance:
 - To support essential program functions such as program evaluation, quality assurance and improvement initiatives, result verification, and test refinement
 - To document proper specimen collection, transport, receipt, and analysis for the benefit of newborns
- If requested by parents for purposes such as:
 - If seeking further genetic testing, as recommended by their health care provider
 - A parent’s desire to participate in research

Research:

The Alaska Newborn Bloodspot Screening Advisory Committee supports a parent's desire to participate in research and honors parental requests to release their child's DBS for research purposes. The advisory committee is not involved with reviewing and approving research requests or verifying that Institutional Review Board (IRB) approval is in place. However, the advisory committee supports protections that are in place for research involving DBS samples. In Alaska, this could involve several entities, such as the Alaska Area IRB at the University of Alaska and any other tribal IRBs, as needed. In addition, the *Newborn Screening Saves Lives Reauthorization Act of 2014* also requires IRB approval for federally-funded research involving blood spots collected after March 17, 2015 (March of Dimes, 2015; National Institutes of Health, 2015).

Dried Bloodspots - Uses Not Permitted

The Alaska Newborn Bloodspot Screening Program does NOT permit the release of DBS for the following:

- Routine paternity testing
- Analysis of medical conditions tested previously by the Oregon Public Health Laboratory (OPHL) in the Newborn Bloodspot Screening process
- Research, unless specifically requested by a parent, as stated above

PROCEDURES:

DBS are securely stored for three years (one year at the OPHL and two years at the Alaska Division of Public Health Laboratory). After three years, the Alaska Division of Public Health Laboratory destroys DBS. Parents requesting a DBS for a child under three years of age should contact the Alaska Newborn Bloodspot Screening Program at <http://dhss.alaska.gov/dph/wcfh/Pages/metabolic/contact.aspx> or call (907) 269 – 3400, and to obtain an Authorization for Release of Dried Bloodspot form.

Security measures are in place at the public health laboratories in Oregon and Alaska. Both laboratories require access through key-cards distributed to employees. Visitors must sign in and out, staff accompanies them, and visitor access is restricted.

To ensure custody of the DBS, one employee from the Perinatal Early Childhood Unit located within the Alaska Division of Public Health, Section of Women's, Children's and Family Health must go to the Alaska Public Health Laboratory to obtain the specimen. Staff will secure the DBS in a secure locked area at WCFH until it is mailed or picked up by the requestor. For specimens less than one year old, The Alaska Newborn Bloodspot Screening Program will work with the OPHL to release specimens.

REFERENCE/STANDARD:

The Secretary of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children recommends that state newborn screening (NBS) programs have a policy related to the use of DBS, including access to DBS after completion of NBS, that ensures family privacy and confidentiality, complies with federal research regulations, and is subject to review by the state's attorney general or other legal authority (Therrell, et al., 2011).

The Association of Public Health Laboratories (APHL) *Residual dried blood spot specimen educational toolkit for newborn screening programs* (2014) provides guidance related to the use of DBS.

http://www.aphl.org/AboutAPHL/publications/Documents/NBS_RDBS_Toolkit_62014.pdf

RELATED POLICIES:

Alaska Statutes and Administrative Code:

<http://www.legis.state.ak.us/basis/statutes.asp>

Alaska Statute, Title 18, Chapter 15

AS 18.15.200 through AS 18.15.210

<http://www.legis.state.ak.us/basis/statutes.asp#18.15.200>

Alaska Admin Code, Title 7, Chapter 27

7 AAC 27.510

<http://www.legis.state.ak.us/basis/aac.asp#7.27.510>

7 AAC 27.530

<http://www.legis.state.ak.us/basis/aac.asp#7.27.530>

7 AAC 27.580

<http://www.legis.state.ak.us/basis/aac.asp#7.27.580>

References/Resources:

Botkin, J.R., Goldenberg, A.J., Rothwell, E., Anderson, R.A., & Huckaby, M. (2013). Retention and research use of residual newborn screening bloodspots. *Pediatrics*, *131* (1), 1-10.

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Lewis, M.H., Goldenberg, A., Anderson, R., Rothwell, E., & Botkin, J. (2011). State laws regarding the retention and use of residual newborn screening samples. *Pediatrics*, *127* (4), 703-712. doi: 10.1542/peds.2010-1468

National Institutes of Health. (2015, July 23). Preliminary guidance related to informed consent for research on dried blood spots obtained through newborn screening. Notice number: NOT-OD-15-127. Retrieved from <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-127.html>

Therrell Jr., B.L., Hannon, W.H., Bailey Jr., D.B., Goldman, E.B., Monaco, J., Norgaard-Pedersen, B., Terry, S.F., Johnson, A., & Howell, R.R. (2011). Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. *Genetics in Medicine*, 13 (7), 621 – 624. Retrieved from <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/residualdriedbloodspots.pdf>

March of Dimes. (2015). Research Involving Newborn Blood Spots. Retrieved from <http://www.marchofdimes.org/materials/March-of-Dimes-NewbornBloodSpots-Paul-Amendment-Fact-Sheet-March-19-2015.pdf>