

Recommendations from the ACHDNC on the Informed Consent Requirement for Use of DBS



Joseph A. Bocchini, Jr. MD
Professor and Chairman
Department of Pediatrics
Louisiana State University Health –
Shreveport
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Newborn Screening Saves Lives Reauthorization Act of 2014

- **Became law December 18, 2014**
- **Reauthorized the Advisory Committee on Heritable Disorders in Newborns and Children**

Reauthorization: Section 12

- Requires federally funded research on newborn dried blood spots to be considered research on human subjects (which requires informed consent of the subject), and eliminates the ability of an IRB to waive informed consent requirements for research on DBS until HHS updates the Common Rule

ACHDNC and Section 12

- Participated in NICHD stakeholder meeting in March 2015
- As a result, the Committee set up a panel of speakers to better understand:
 - Why the amendment was added
 - NBS lab procedures and QI processes
 - Challenges faced by state NBS programs conducting pilot studies

May 2015 ACHDNC Meeting

- **Overview of Newborn Screening Laboratory Processes and Quality Management (Scott Shone, PhD)**
- **Amendment 12 of the NBS Saves Lives Reauthorization Act of 2014: Landscape and Potential Implications (Michelle Huckaby Lewis, MD, JD)**

Dried Bloodspot Controversy

- **Parents poorly informed about retention/use**
- **Until recently, under Common Rule, research conducted using de-identified DBS was not considered human subjects research; consent not needed**
- **Privacy advocates have objected to research use and release of de-identified DBS to researchers w/o parental consent**
- **Litigation in 3 states: TX, MN, IN**
 - **Destruction of millions of retained DBS**
 - **New laws require consent in TX & MN for research use**

May 2015 ACHDNC Meeting

- **Summary of the Secretary's Advisory Committee on Human Research Protections Meeting on the NBS Informed Consent Amendment (Jeff Botkin, MD)**
- **SACHRP Recommendations Regarding Research Uses of Newborn Dried Bloodspots and the Newborn Screening Saves Lives Reauthorization Act of 2014**

May 2015 ACHDNC Meeting

- **Texas Opt-In Methodology for Sample Storage and Research (Susan Tanksley)**
- **Michigan Opt-In Methodology for Sample Storage and Research (Carrie Langbo)**
- **California – Proposed Bill at State Legislature (Fred Lorey)**

ACHDNC Recommendation #1

**The Secretary of HHS should adopt the
“SACHRP Recommendations
Regarding Research Uses of Newborn
Dried Bloodspots and the Newborn
Screening Saves Lives Reauthorization
Act of 2014”**

ACHDNC Recommendation #2

- **The Secretary of HHS should work with States to develop guidance for Institutional Review Boards that**
 - **distinguishes between research and non-research in the context of required, routine newborn screening program activities such as quality assurance, quality improvement and method development for new screening tests.**

ACHDNC Recommendation #3

- **The Secretary of HHS should work with States to develop guidance for Institutional Review Boards that**
 - **identifies appropriate models for broad or blanket informed consent for using residual dried blood spots to (1) develop new methods or (2) perform newborn screening research.**

ACHDNC Recommendation #4

- **The Secretary of HHS should work with States to develop guidance for Institutional Review Boards that**
 - **identifies appropriate models for broad or blanket informed consent for states that choose to store residual dried blood spots for future research purposes.**

ACHDNC Recommendation #5

- **The Secretary of HHS should create and distribute communication materials on the importance of newborn screening and options to participate in research to professional organizations associated with obstetricians, nurses, midwives, and other health care workers who care for pregnant women and the public.**

ACHDNC Recommendations #6

- **Encourage states to monitor:**
 - **How requiring informed consent for storage of NBS samples for future research impacts clinical newborn screening rates**
 - **Who consents and who does not allow long-term storage of NBS samples for future research**
 - **What communication and educational materials are needed so the overall newborn screening rate remains high**
 - **Determine whether the stored NBS samples reflect the US newborn screening population.**

ACHDNC Recommendations #7

- **The Secretary of HHS should consider mechanisms by which biomedical research could be funded as it relates to informed consent education of parents on newborn screening and use of to residual DBS**



U.S. Department of Health and Human Services

Advisory Committee on Heritable Disorders in Newborns and Children

Thank You!