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NATIONAL CONVERSATION ON NEWBORN SCREENING RESEARCH AND INFORMED CONSENT

June 1-2, 2015

Meeting Overview

- Background (Section 12, NBSSLA)
- Objectives
- Outline
- Logistics
- Introductions



Section 12 | NBSSLA 2014

The informed consent provisions included in the Newborn Screening Saves Lives Reauthorization Act went into effect on March 16, 2015. The law includes two significant changes to the human subjects regulations as they apply to research with newborn dried blood spots.



Section 12 | NBSSLA 2014

- All research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable.

Section 12 | NBSSLA 2014

- The law eliminates the ability of the IRB to approve alterations or waivers of informed consent for research involving newborn dried blood spots.

The purpose of this meeting is to convene pertinent stakeholders to discuss the informed consent provisions, their interpretation, implications and impact on newborn screening.

Meeting Objectives

- Understand State concerns and anticipated implications of the Newborn Screening Saves Lives Act Amendment.
- Describe the impact of the Law on Federally funded research activities.
- Discuss the impact of the Law on State Institutional Review Boards (IRBs)



Meeting Objectives

- Outline routine newborn screening laboratory activities that require usage of residual dried blood spots.
- Discuss issues related to broad consent for future use of residual dried blood spots.
- Identify needs and strategies to educate the public about newborn screening, and options to participate in newborn screening research

Meeting Outline

- Introduction and Background on the 2014 Newborn Screening Saves Lives Act Amendment (Section 12)
- State and Federal Considerations Regarding the New Amendment for State Newborn Screening Programs

Meeting Outline (contd.)

- What Constitutes Newborn Screening
Research: An evaluation of essential program activities for screening of current and new conditions.
- Informed Consent for Newborn Screening
Research: Examples of a Broad Consent Package

Meeting Outline (contd.)

- Open discussion on items to consider when developing broad informed consent models for newborn screening research
- Educating the Public about Newborn Screening: Current and Proposed Communication Strategies



APHL Legal and Legislative in NBS Workgroup

- Sue Berry, MN
- Victoria Buchanan, IN
- Denise Chrysler (co-chair)
- Anne Comeau, MA
- Amy Gaviglio, MN
- Aaron Goldenberg
- Michal Hayes, NM
- Michelle Huckaby-Lewis
- Kimberly Jenkins, NJ
- Donna Levin
- Kelly MacKinnon, IN
- Elizabeth Maynard, NH
- Julie Meadows-Keefe
- Lea Mott, KY
- Kimberly Noble Piper, IA
- Dave Orren, MN (co-chair)
- Brenda Romero, NM
- Beth Tarini



Thanks

- Scott Shone, NJ
- Stan Berberich, IA
- Patrick Hopkins, MO
- Mei Baker, WI
- Anne Comeau, MA
- Bob Currier, CA
- Mark McCann, MN
- Michele Caggana, NY
- Susan Tanksley, TX
- Peter Kyriacopoulos
- Carla Cuthbert, CDC
- APHL NBSG
Colleagues



Meeting Logistics

- Presentations
- Reimbursement
- Wifi
 - Consent2015
- Questions



Introductions



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