Newborn Screening Saves Lives - Act II
“What is Newborn Screening Research?”

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NICHD hosted a meeting March 9th 2015

• Newborn Screening Saves Lives Reauthorization Act of 2014 signed into law December 2014

• NIH hosted a meeting on March 9 to explore the optimal timing and method of obtaining informed consent to meet the law’s new provision

• Brought together wide range of stakeholders from research, public health, and policy

• Result – more questions than answers
What are the changes

• Before March 17
  • Studies using deidentified NBS dried blood spots may be considered as not “human subjects” research
  • IRBs authorized to waive consent

• After March 17
  • Studies using deidentified NBS dried blood spots must be viewed as human subjects research
  • IRBs may not authorize waived consent
Identifying what is “Research” is challenging
Goals of the Hunter Kelly Newborn Screening Research Program

- Identify, develop and test the most promising technologies
- Increase the specificity of newborn screening and expand the number of conditions for which screening tests are available
- Develop experimental treatments and disease management strategies for additional newborn screening conditions, and other genetic, metabolic, hormonal and/or functional conditions that can be detected through newborn screening for which treatment is not yet available
- Provide research findings and data for newborn screening conditions
- Conduct pilot studies on conditions recommended by the ACHDNC to ensure screening are ready for nationwide implementation
Where is the line in the sand?
Questions identified in the meeting

- What is the intent of the law?
- What is the impact of the law on public health?
- What is research?
  - What is “Federally funded research”
- “Informed consent”
  - How informed is informed?
  - What type of consent is acceptable?
  - When and how is the best way to obtain consent?
- What about the “Common Rule”
Next Steps for NIH

• Meeting summary, outlining major questions, will be posted on NICHD website
• NIH working with OHRP to provide further guidance to the field
• Continuing to support permissible activities until consent issues clarified
Balancing Act

Science

Human Subject Protection

Ethics