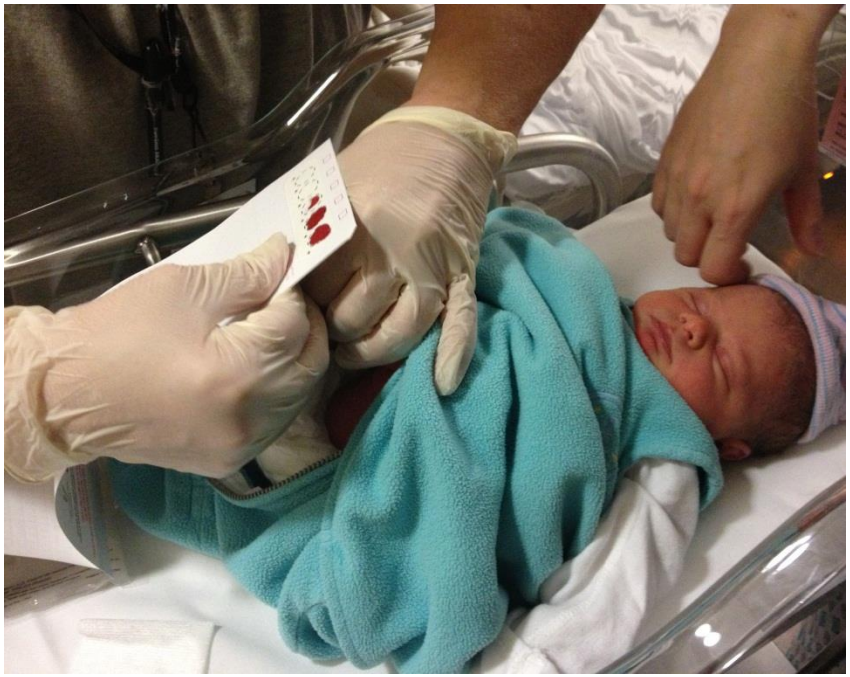
Newborn Screening Saves Lives -Act II
"What is Newborn Screening Research?"



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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