



# **A NATIONAL CONVERSATION ON NEWBORN SCREENING RESEARCH AND INFORMED CONSENT**

## **RECAP & DISCUSSION**



Dave Orren  
June 2, 2015

# MEETING OBJECTIVES

- Understand State concerns of the NBSSLRA.
- Describe impact on Federally funded research.
- Discuss impact on State IRBs.
- Discuss whether NBS lab activities may be research or non-research.
- Discuss broad consent for future use of residual DBS.
- Identify ways to educate public about NBS and options to participate in NBS research.

# RECAP

## AGENDA DAY 1: MONDAY, JUNE 1, 2015 NEW HAMPSHIRE BALLROOM

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HOST: Jelili Ojodu, MPH, Association of Public Health Laboratories

- 8:00 Breakfast (served New Hampshire Ballroom)
- 8:30 Welcome
- Statement of Newborn Screening Saves Lives Act
  - Statement of broad concerns
  - Scope of meeting
  - Desired outcomes of meeting
- 8:40 Participant Introductions
- 9:00 Introduction to and Background on the 2014 Newborn Screening Saves Lives Act Amendment (Section 12)
- 9:00 The development of the language for the Newborn Screening Saves Lives Act Amendment | Peter Kyriacopoulos, Association of Public Health Laboratories
- 9:15 Summary and Highlights of the National Institutes of Health (NIH) Meeting on Informed Consent | Tiina Urv, PhD, National Institutes of Health, US Department of Health and Human Services
- 9:25 Recommendations from the Secretary's Advisory Committee on Human Research Protections Meeting and Discussion of Implications | Michelle Huckaby-Lewis, MD, JD, Johns Hopkins University
- 9:45 Recommendations from the Advisory Committee on Heritable Disorders in Newborns and Children Meeting and Discussion of Implications | Joseph A. Bocchini, Jr., MD, Advisory Committee on Heritable Disorders in Newborns and Children
- 10:00 Comments and Questions
- 10:15 Break
- 10:30 State and Federal Considerations Regarding the New Amendment for State Newborn Screening Programs  
*This session will feature presentations providing a background and information on state and federal stakeholders.*

# RECAP

10:30	Overview of routine program activities in newborn screening, as required for CLIA/CAP compliance, quality improvement and program expansion   Michele Caggana, ScD, FACMG, <i>New York State Department of Health</i>
10:50	Food and Drug Administration (FDA) Laws pertaining to human research protection, the use of investigational devices and considerations for use of Laboratory Developed Tests (LDTs)   Kellie Kelm, PhD, <i>Food and Drug Administration, US Department of Health and Human Services</i>
11:15	Office for Human Research Protections (OHRP) role and considerations in the definition of research   Jerry Menikoff, MD, JD, <i>Office for Human Research Protections, US Department of Health and Human Services</i>
11:45	Comments and Questions
12:00	Lunch (served New Hampshire Ballroom)
1:00	<b>What Constitutes Newborn Screening Research: An evaluation of essential program activities for screening of current and new conditions.</b> <i>This session will constitute a review of a variety of newborn screening scenarios and discussion regarding research implications. State, OHRP and FDA perspectives will be considered and discussed.</i>  Newborn Screening Programs Scenario Overview and Proposed Classifications   Susan Tanksley, PhD, <i>Texas Department of State Health Services</i>
2:30	Break
3:00	(Continued) Newborn Screening Programs Scenario Overview and Proposed Classifications   Susan Tanksley, PhD, <i>Texas Department of State Health Services</i>
4:30	Adjourn

# LOOKING AHEAD

AGENDA DAY 2: TUESDAY, JUNE 2, 2015

NEW HAMPSHIRE BALLROOM

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HOST: Jelili Ojodu, MPH, Association of Public Health Laboratories

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| 8:00  | <b>Breakfast (served New Hampshire Ballroom)</b>   |
| 8:30  | <b>Recap of Day 1 and Discussion</b>   Dave Orren, JD, Minnesota Department of Health  |
| 8:45  | <b>Informed Consent for Newborn Screening Research: Examples of a Broad Consent Package</b><br><i>This session will focus on contents and requirements of a comprehensive informed consent package for States endeavoring to perform newborn screening research.</i>                             |
| 8:45  | <b>Experience from Texas</b>   Susan Tanksley, PhD, Texas Department of State Health Services  |
| 9:15  | <b>Experience from Massachusetts</b>   Anne Comesu, PhD, University of Massachusetts Medical School  |
| 9:45  | <b>Experience from Michigan</b>   Carrie Langbo, MS, CGC, Michigan Department of Health and Human Services   |
| 10:15 | <b>Comments and Questions</b>  |
| 10:30 | <b>Break</b>   |
| 10:45 | <b>Open Discussion on items to consider when developing broad informed consent models for newborn screening research</b><br><br>Michelle Huckaby-Lewis, MD, JD, Johns Hopkins University<br>Dave Orren, JD, Minnesota Department of Health<br>Denise Chrysler, JD, Network for Public Health Law |
| 12:00 | <b>Lunch (served in New Hampshire Ballroom)</b>  |
| 1:00  | <b>Educating the Public about Newborn Screening: Current and Proposed Communication Strategies</b><br><i>This session will focus on public outreach and educational initiatives as they relate to newborn screening and informed consent.</i>  |
| 1:00  | <b>Communication Strategies for Newborn Screening – Where do we go from here?</b>   Natasha Bonhomme, Genetic Alliance   |



# LOOKING AHEAD

- 1:20 Saving Babies Through Screening Educational Activities and Perspectives on Informed Consent | Jill Levy-Fisch, BA, *Save Babies Through Screening Foundation*
- 1:35 Parental preference on research consent: Empirical research | Aaron Goldenberg, PhD, MPH, *Case Western Reserve University*
- 1:55 Engaging the Public/Parents and Enlisting Providers | Carrie Langbo, MS, CGC, *Michigan Department of Health and Human Services*
- 2:15 Awareness, Education, and Training on Newborn Screening | Amy Gaviglio, MS, CGC, *Minnesota Department of Health*
- 2:15 Open discussion on identifying strategies and engaging advocates in targeted organizations: nurses, midwives, childbirth educators, family physicians and other health care professionals | Natasha Bonhomme, *Genetic Alliance*
- 2:45 Next steps and closing
- 3:00 Adjourn



If You Are Permitted:

# Advocate During Common Rule Comment Period

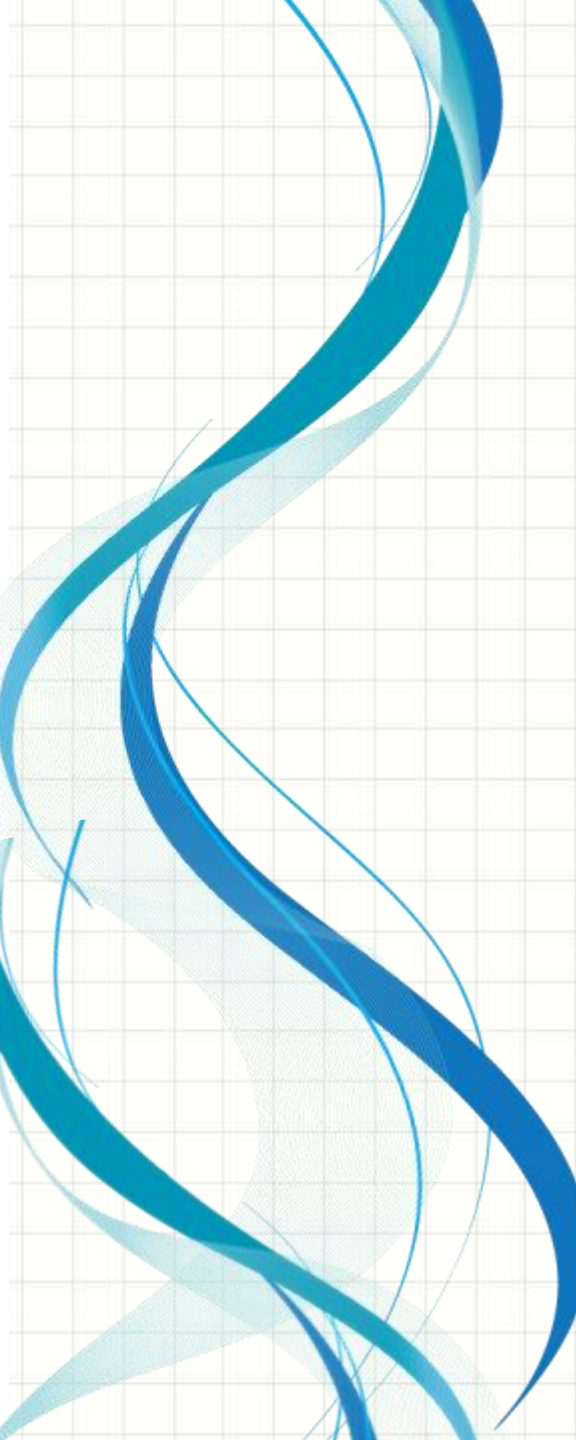
(Genetics/Genomics Require Wisdom, Balance)

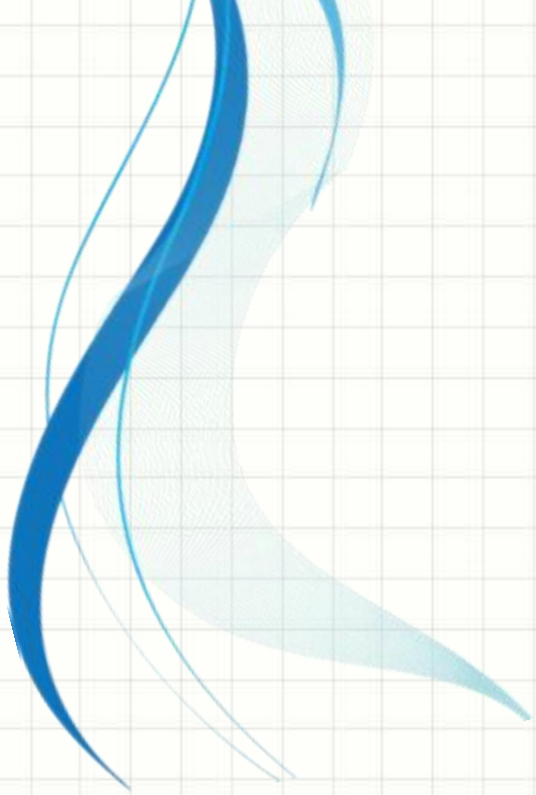


# Proudly Saving Babies Since 1964

- Your Newborn Screening  
Government Program



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- ✓ Worthy of Trust
  - ✓ Transparent
  - ✓ Open to Suggestions
  - ✓ Willing to Improve



**Thank You!**