Michigan BioTrust For Health

National Conversation on Newborn Screening Research and Informed Consent

Informed Consent for Newborn Screening Research: Examples of a Broad Consent Package

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June 1, 2015

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

Michigan BioTrust for Health

- Formally launched June 1, 2009
- MDHHS initiative to oversee storage & use of residual newborn screening blood spots
  - Preserve and promote research use
  - Increase community awareness and engagement
  - Use in a manner acceptable to the public
  - Improve decision-making processes

Public Health Rep. 2013 Sep-Oct; 128(5): 377–384

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Motivation for Developing BioTrust

Perspective from Michigan

- Enabling legislation
  - Public Health Code 333.5431*(7)(1)(a)(b)* and *(8)(d)*
- Advances in technology made blood spots more useful
  - Increasing interest led to more requests
- Storage facility was scheduled to close
- Ensure citizen involvement in developing policies governing use of stored blood spots

Motivation for Other States

- Identify necessity for storage
  - Is the programmatic use of residual blood spots considered research?
  - If no, do *all* states want or need blood spots for research use?
- Contribute to medical and public health research
- Respond to issues unique in a state
  - Disease outbreaks, environmental issues

Assess Community Attitudes

Michigan Efforts 2008-2009

Michigan Behavioral Risk Factor Survey (n=3,108)

- State-level, random digit-dialed telephone survey of adults
- 4 questions about the level of support for blood spot use
  - General research: 72.3% favored
  - Childhood diseases/conditions: 84.9% favored
  - Diseases typically developing in adulthood: 86.8% favored
  - Environmental research: 84.2% favored
- Support by demographics
  - Lowest among those in youngest and oldest age groups
  - Higher among whites compared with blacks and other non-whites
  - Increased consistently with increasing education and household income

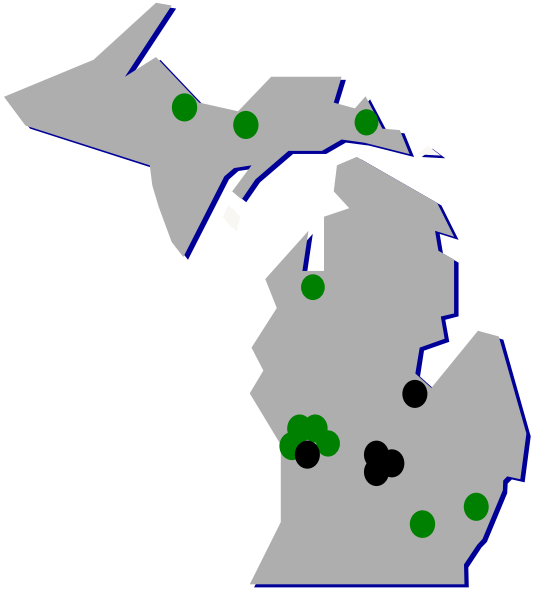
Public Health Genomics. 2011;14(3):143-52

Engage Your Community

Michigan Efforts 2008-2009

Focus groups convened to gauge support for research use (n=86)

- General public that might have potential concerns as stakeholders
- 61.7% strongly and 24.7% somewhat supported use
- Strong consensus for informing parents
  - 55% favored opt-out model
  - 16% found opt-out or opt-in model acceptable
  - 29% favored opt-in model



Public Health Genomics. 2012;15(3-4):146-55

Solicit Community Feedback

Michigan Efforts 2008-2009

Presentations (n=55)

- Advocacy, health professional and businessmen groups
- 94-96% supported research on environmental factors and childhood or adult-onset conditions

On-line Survey (n=330)

- 26 question web-based survey distributed to ~60 health professional and other organizations
- ~79% respondents would allow research use of their own or their child's blood spots

Enlist Advisory Boards

- Community engagement workgroup
  - Community Values Advisory Board (CVAB), established June 2009

American Cancer Society	American Indian Health & Family Services	Arab Comm. Center for Economic & Social Services	Cristo Rey (Hispanic Community Health Centers)
Michbio (Organization for Biosciences Industry)	MI Assoc. of Black Social Workers	MI Assoc. of Genetic Counselors	MI Assoc. Local Public Health
MI Council for Maternal & Child Health	MI Developmental Disabilities Council	MI Environmental Council	MI Health and Hospital Assoc.
MI Minority Health Coalition	The Network for Public Health Law	Genetic Counseling Grad Program(s) Student Reps	2 Members-at-Large *1 Member-at-Large U.P.*

- Scientific workgroup
  - Scientific Advisory Board, established February 2010

Enlist Advisory Boards

- MDHHS Institutional Review Board
  - Formal determination regarding consent process
  - Review proposals for compliance with regulations governing research
  - Review proposals for concerns to groups, not just individuals
  - CVAB representative on MDHHS IRB
  - Oversight and annual renewal
    - Waiver of consent for archived specimens
    - Adequate measures to inform public
    - Consent process including birthing hospital performance
    - Quality metrics on linking to consent decision/image

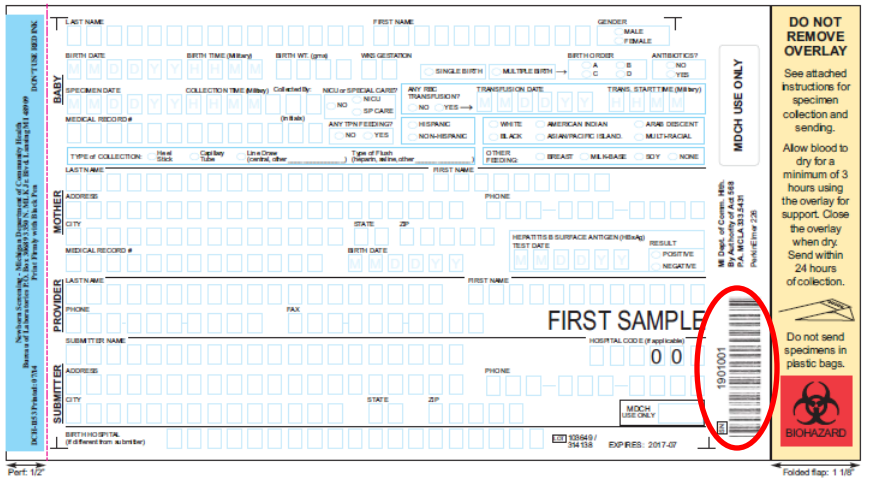
Consideration of Consent Models

- MDHHS Institutional Review Board
  - 9/2008 OHRP guidance: "*MI proposed repository in manner described, would involve non-exempt human subject research…your project would require review and approval by an IRB...The IRB must determine that informed consent will be sought…or find and document that criteria for a waiver of informed consent …are satisfied*."
  - IRB determination: BioTrust is human subjects research and no waiver of informed consent issued for prospectively collected samples. Waiver issued for specimens collected prior to consent process.

Removed option of opt-out process for prospectively collected samples.

Informed Consent Approaches

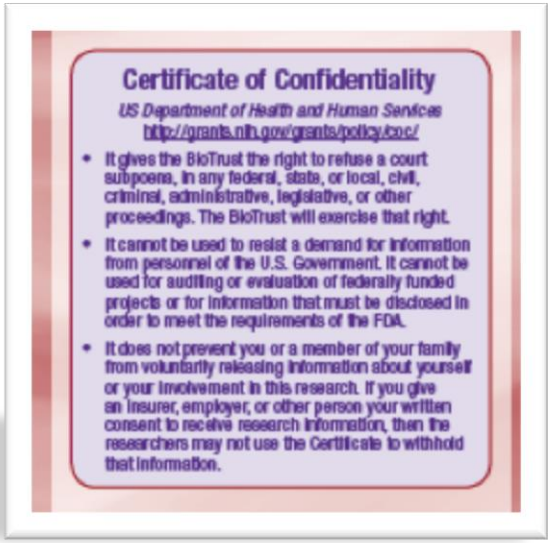
- Consent collected prenatally
  - Pros:
    - Timing/multiple visits
    - Parental state of mind
  - Cons:
    - No sample
    - NBS Card cannot be issued prenatally
    - Tracking
    - Coding and linking



Determined approach is not logistically feasible.

Informed Consent Approaches

- Consent part of NBS card
  - Pros:
    - One document
    - Code, track and link to blood spot
    - Decreased costs if no brochure
  - Cons:
    - Space restricts font size, graphics and text
    - Certificate of Confidentiality required language
    - Separation/distinction with NBS



Determined approach is reasonable but not optimal for our state.

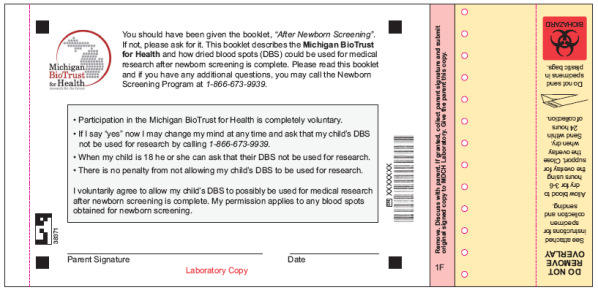
Informed Consent Approaches

- Consent brochure with:
  - Consent collected as electronic birth certificate field

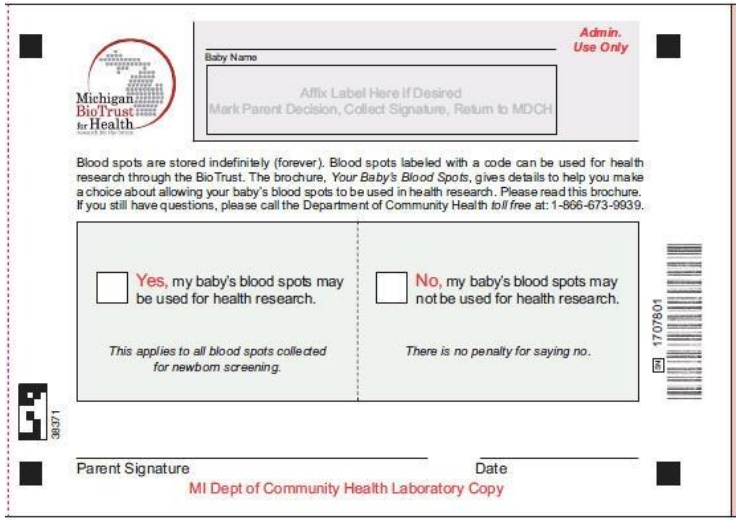
    Determined potentially coercive.

  - Consent collected on NBS card

    Determined documentation of refusal was also needed.



Current BioTrust Consent Process



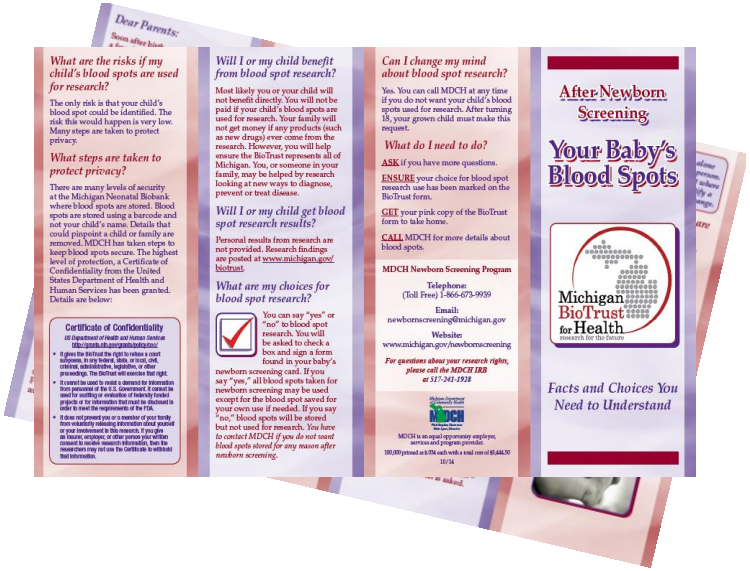
www.michigan.gov/biotrust

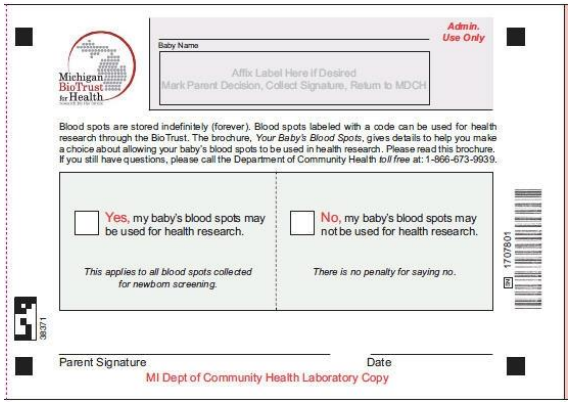
- Separate consent brochure & declaration form in NBS card

Determined most practicable method for obtaining & documenting informed consent.

Current BioTrust Consent Process

- Consent brochure allows:
  - Space for detailed information
  - Distinction from NBS
  - Dissemination at multiple points
- Consent declaration form allows:
  - No delay in NBS
  - Coding, tracking, linking to blood spot
  - Ability to ensure parent was asked by documenting “yes” or “no” decision





Current BioTrust Consent Process

- Approved originally with no IRB waivers
  - Brochure given in advance of signature, available at time of signature and it's clear signature is in reference to brochure
- MDHHS will continue to administer consent process facilitated by birthing hospitals and home-birth attendants
- MDHHS will formally assess consent material once federal guidance is received.
  - In interim, MDHHS will review specific studies requesting blood spots collected after March 15, 2015, to determine if BioTrust consent for that study is adequate under new law or whether additional consent is required

Michigan BioTrust for Health

- Consent rate, first quarter 2015
  - 84% of BioTrust consent forms returned completed
  - **66%** of newborns screened have BioTrust consent on record
  - 18% of newborns screened have BioTrust refusal on record
  - 16% of newborns screened have no BioTrust decision on record
    - Blood spots stored indefinitely, ***not*** used for research through BioTrust
- Consent versus screened populations, 2014
  - 5% more white newborns
  - 4.6% less black newborns
  - 1% less Arab newborns
  - Ethnicity and maternal age similar

Success is measured by the ability to make an informed decision

Questions

- Is broad, *not blanket*, consent for future research use acceptable?
- How best do you incorporate the required elements in a broad consent form for future unspecified research?
  - 45cfr46.116(a)(1) A statement that the study involves research, an *explanation of the purposes of the research* and the expected duration of the subject's participation, *a description of the procedures to be followed*, and identification of any procedures which are experimental;

Michigan BioTrust for Health

Thank you!

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