

# Michigan BioTrust For Health

## *Opt-in Methodology for Residual Newborn Screening Blood Spot Storage and Research Use*

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# Michigan BioTrust for Health

- Public Health Code 333.5431(7)(1)(a)(b) and (8)(d)
  - MDHHS may set the retention period
  - Residual stored blood spots may be used for research
  - NBS brochure must mention medical research use
- 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
  - Improve decision-making processes





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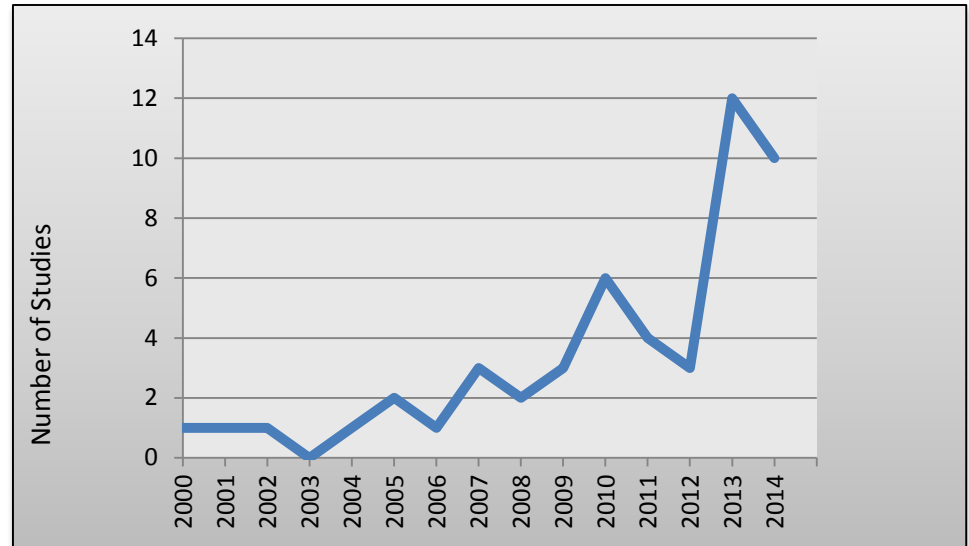
- Michigan blood spots
  - Coded to remove identifying information
  - Stored at Michigan Neonatal Biobank
    - Archived pool (July 1984-April 30, 2010), *opt-out*
    - Consented pool (May 1, 2010- present day), *opt-in*
  - Approximately 5 million samples
  - Spot stored at MDHHS for use by parent





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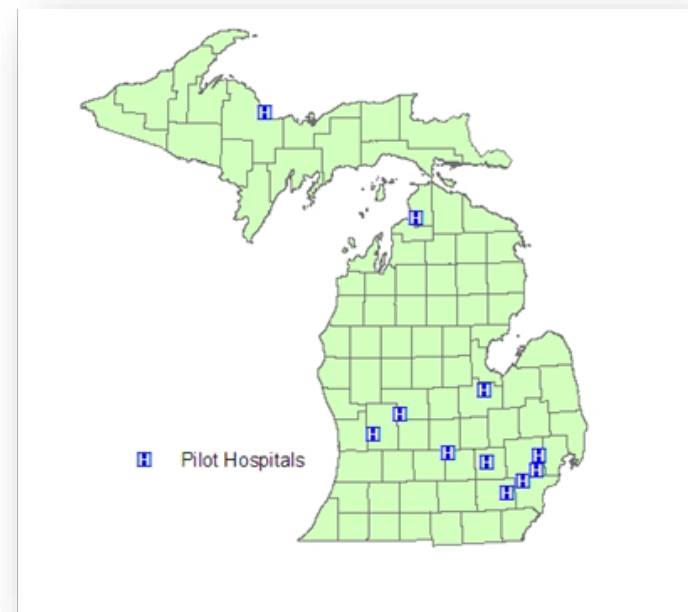
- Review process
- Coding process
- 2013-2014 studies
  - 22 approved
  - 4/22, federally funded
  - 19/22, academia
  - 2/22, private industry
  - 2/22, state NBS program





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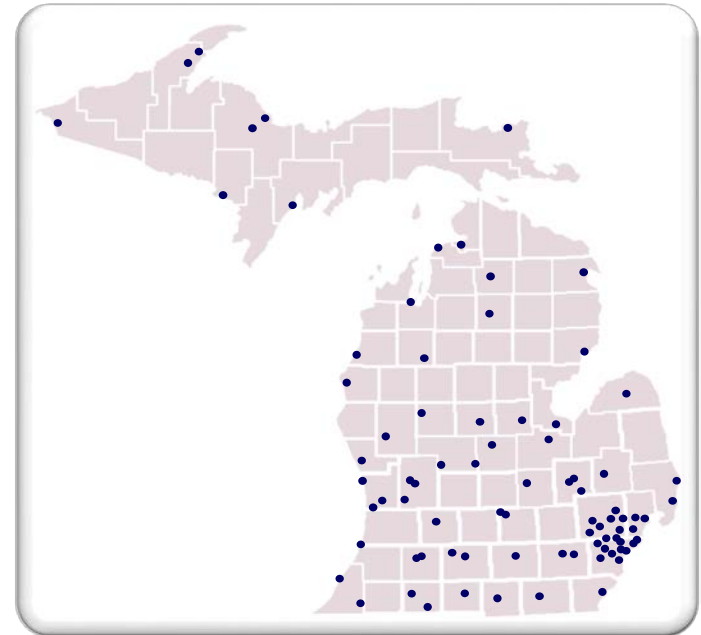
- Consent brochure & form
  - Advisory board input, focus group testing, printing
- Early Implementation (Pilot)
  - May 1, 2010 to July 5, 2010
  - 11 hospitals
  - Identify best-practice guidelines
    - Staff wanted record of dissent
  - In-service training by MDHHS
  - Encounter information reported
    - ~80% encounters required <5 minutes to answer any remaining questions after reading consent brochure





# Michigan BioTrust for Health

- Statewide Implementation
  - Deadline of October 1, 2010
  - Director's letter to hospital CEOs
  - 100% enrollment in MDHHS training
    - 29% in-service
    - 62% on-line module
    - 9% webcast
    - >650 nursing CEs
  - Daily after hours hot-line
  - Homebirths





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A declaration form for blood spots. It includes a header with the Michigan BioTrust for Health logo, a section for "Baby Name" with a line for text and a note "Admin. Use Only", and a central area with two checkboxes: "Yes, my baby's blood spots may be used for health research." and "No, my baby's blood spots may not be used for health research." Below these are the statements "This applies to all blood spots collected for newborn screening." and "There is no penalty for saying no." The form also has fields for "Parent Signature" and "Date", and a barcode on the right side with the number "1707801".

[www.michigan.gov/biotrust](http://www.michigan.gov/biotrust)

- Prenatal introduction with consent process after delivery
- Separate consent brochure & declaration form in NBS card



# Michigan BioTrust for Health

- First Quarter 2015
  - 84% of BioTrust consent forms returned completed
    - 88% of hospitals returned >80% completed
    - 48% of hospitals returned >90% completed
  - **66%** of newborns screened have BioTrust consent on record
    - Blood spots stored indefinitely and made available for approved research through the BioTrust
  - 18% of newborns screened have BioTrust refusal on record
    - Blood spots stored indefinitely and **not** used for approved research through the BioTrust
  - 16% of newborns screened have no BioTrust decision on record
    - Blood spots stored indefinitely and **not** used for approved research through the BioTrust





# Michigan BioTrust for Health

- Key elements to consider
  - Hospital engagement in research
  - Process delaying NBS
  - Distinguish NBS from BioTrust
  - Track & code specimen
    - NBS card number printed on form
  - Monitor hospital performance
    - Mechanism to ensure parents asked
    - Provide hospitals on-going feedback
    - Maintain hospital training

The image shows a white form for newborn blood spots (NBS) and a purple brochure. The form includes a header with the Michigan BioTrust for Health logo and a "Baby Name" field. Below this is a section for "Admin. Use Only" with instructions to "Affix Label Here If Desired" and "Mark Parent Decision, Collect Signature, Return to MDCH". The main body of the form contains two columns of text with checkboxes. The left column asks "Yes, my baby's blood spots may be used for health research." and the right column asks "No, my baby's blood spots may not be used for health research." A barcode is located on the right side of the form, circled in red. At the bottom of the form, there are fields for "Parent Signature" and "Date", and a note that the form is a "MI Dept of Community Health Laboratory Copy". The purple brochure, titled "Your Baby's Blood Spots", features the Michigan BioTrust for Health logo and the text "Facts and Choices You Need to Understand".



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*Thank you!*

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