Newborn Screening Biospecimens and Broad Consent

The Michigan BioTrust for Health Consent Process as Perspective on the Common Rule Notice of Proposed Rulemaking (NPRM)

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

Michigan BioTrust for Health

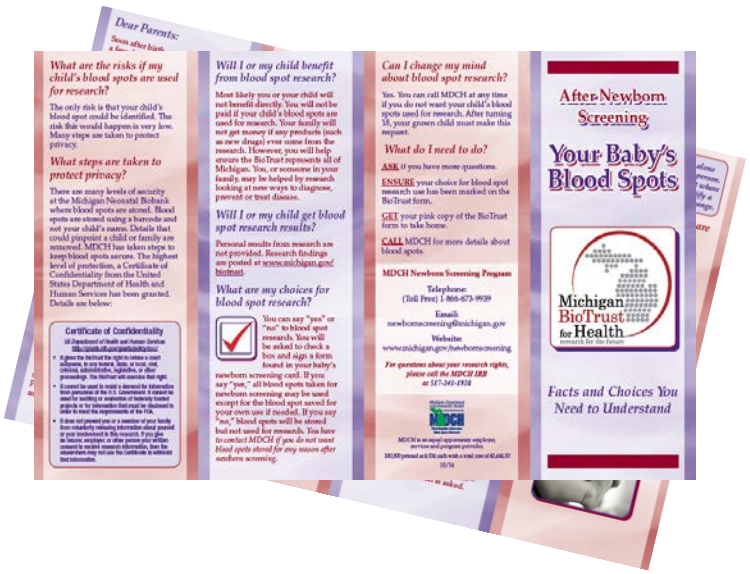
- MDHHS initiative to oversee storage & research use of residual newborn screening blood spots
  - Preserve specimens and promote research use
  - Increase community awareness and engagement
  - Use in a manner acceptable to individuals/public
  - Operate within regulatory requirements

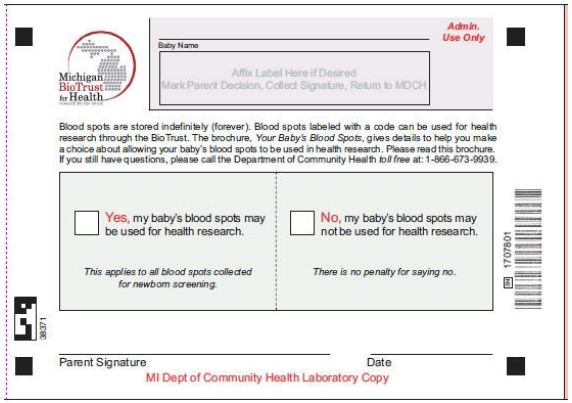
- Guided by a Community Values Advisory Board, Scientific Advisory Board, and Institutional Review Board

- Implemented with support from Michigan's >80 birthing hospitals and among those facilitating home births

Original BioTrust Consent Process

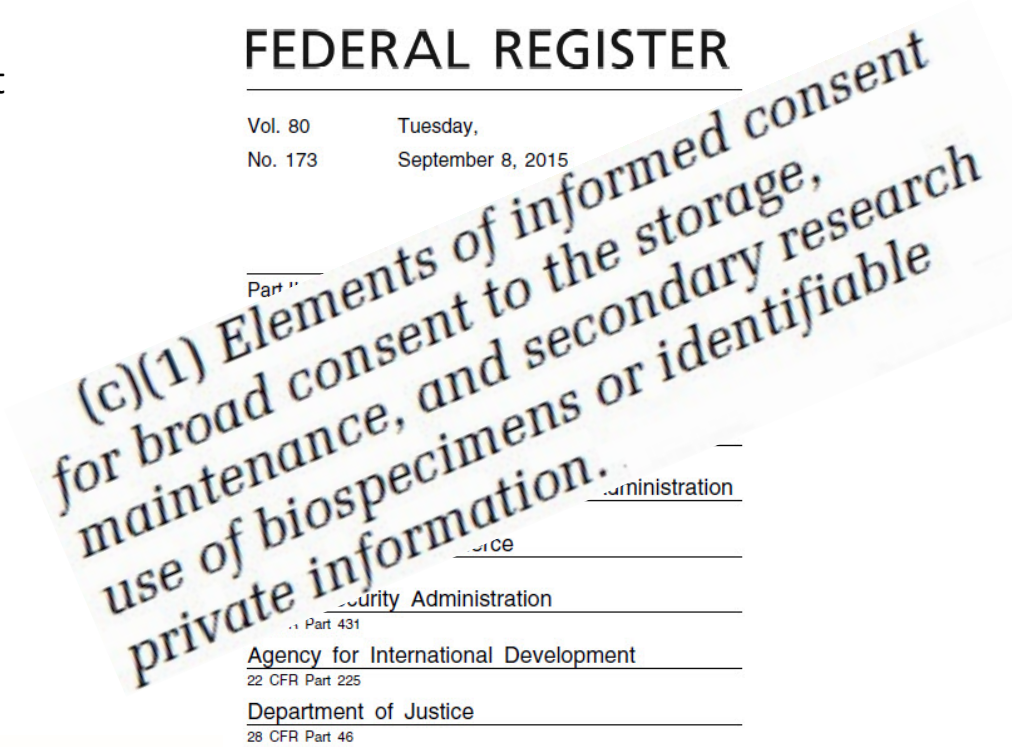
- Consent brochure allows:
  - Space for detailed information
  - Distinction from NBS
  - Dissemination at multiple points
- Consent declaration form allows:
  - No delay in NBS
  - Coding, tracking, linking to blood spot
  - Ability to ensure parent was asked by documenting “yes” or “no” decision
- Waiver of consent for archived specimens allows:
  - Preservation and limited research use of specimens for which consent is not practicable





Notice of Proposed Rulemaking

- Revision of the definition of human subject
- New privacy and confidentiality standards
- Revised requirements for informed consent
- Partial IRB review of exempt research involving biospecimens
- Elements of informed consent for broad consent to the storage, maintenance, and secondary research use of biospecimens or identifiable private information
- End result is an extremely complex set of rules…



NPRM Broad Consent Requirements

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw consent, if feasible, for research use or distribution of the subject's information or biospecimens at any time without penalty or loss of benefits to which the subject is otherwise entitled, and information about whom to contact in order for the subject to withdraw consent. The statement must make clear that information or biospecimens that already have been distributed for research use may not be retrieved;

NPRM Broad Consent Requirements

- A general description of the types of research that may be conducted with information and biospecimens and the information that is expected to be generated from the research, the types of information or biospecimens that might be used in research, and the types of institutions that might conduct research with the biospecimens or information;

- A clear description of the types of biospecimens or information that were or will be collected and the period of time during which biospecimen or information collection will occur.

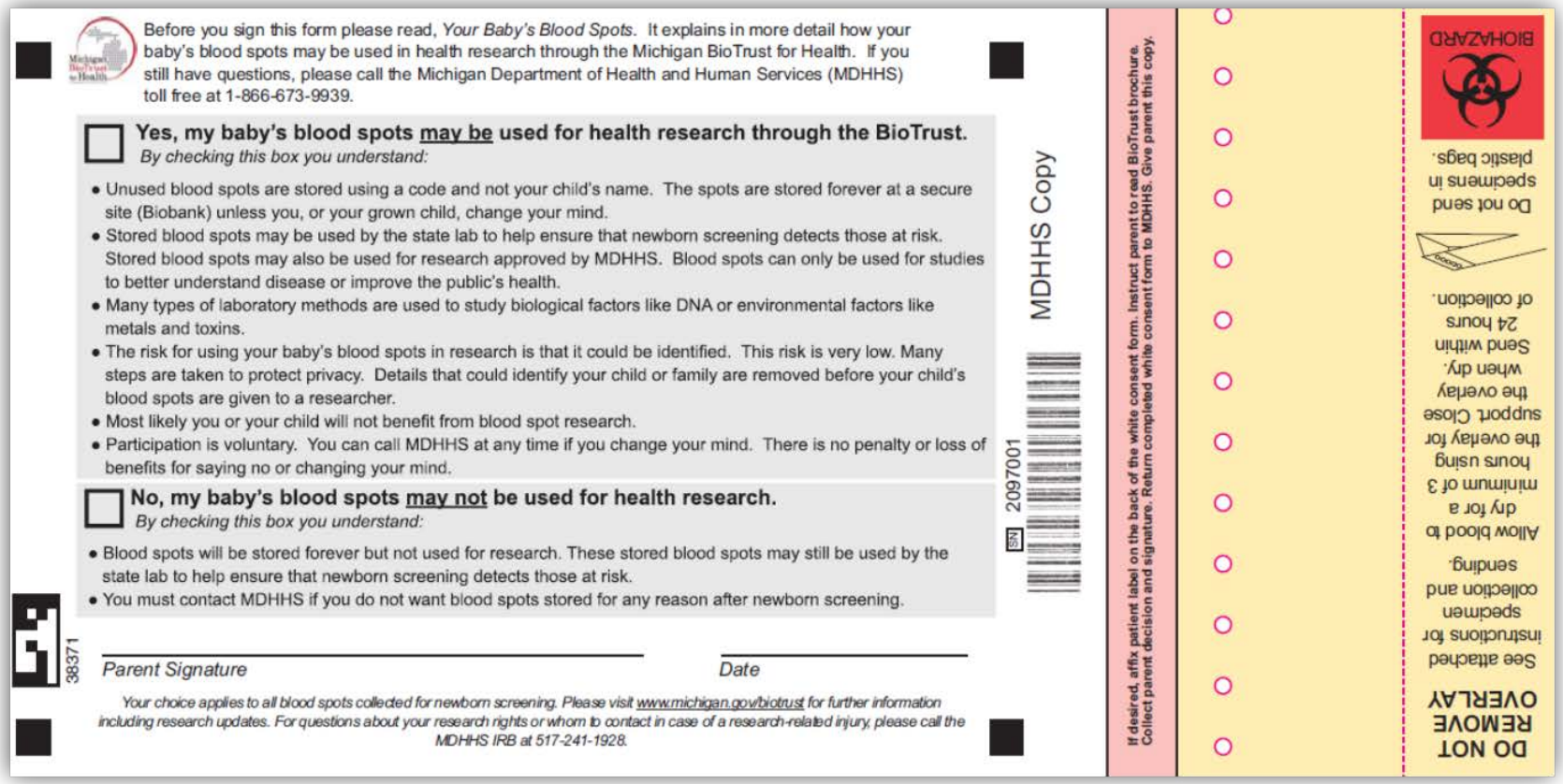
- A description of the period of time during which an investigator can continue to conduct research using the subject's biospecimens and information (e.g., a certain number of years, or indefinitely);

- The names of the institution or set of institutions at which the subject's biospecimens or information were or will be collected, to the extent possible (in recognition that institutions might change names or cease to exist).

NPRM Broad Consent (if applicable)

- A statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit (if applicable);
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (if applicable);
- An option for the subject or the representative to consent, or refuse to consent, to investigators re-contacting the subject to seek additional information or biospecimens or to discuss participation in another research study (if applicable);
- If applicable, a statement notifying the subject or the representative that the subject or the representative will not be informed of the details of any specific research studies that might be conducted, including the purposes of the research, that will use the subject's information and biospecimens;
- If applicable, a statement notifying the subject or the representative of the expectation that the subject's information and biospecimens are likely to be used by multiple investigators and institutions and shared broadly for many types of research studies in the future, and this information and the biospecimens might be identifiable when shared;

Michigan BioTrust for Health Revisions: What's on the form…



Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

☐ **Yes, my baby's blood spots may be used for health research through the BioTrust.**
By checking this box you understand:

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

☐ **No, my baby's blood spots may not be used for health research.**
By checking this box you understand:

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

38371

Parent Signature _____ *Date* _____

Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.

MDHHS Copy

SN 2097001

If desired, affix patient label on the back of the white consent form. Instruct parent to read BioTrust brochure. Collect parent decision and signature. Return completed white consent form to MDHHS. Give parent this copy.

DO NOT REMOVE OVERLAY

See attached instructions for specimen collection and sending.

Allow blood to dry for a minimum of 3 hours using the overlay for support. Close the overlay for when dry. Send within 24 hours of collection.

Do not send specimens in plastic bags.

BIOHAZARD

Michigan Department of Health & Human Services
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Michigan BioTrust for Health Revisions: What isn't on the form…

- The "if applicable" sections of the NPRM requirements
  - Handled through institutional policy
    - Limitations on types of permissible research
    - Prohibitions on follow-up without obtaining research specific informed consent in advance
    - Prohibitions on types of analysis without obtaining research specific informed consent in advance
- Information not necessary to understanding the potential for research use of specimens

NPRM and Waiving Consent Requirements for Biospecimens

- The MDHHS IRB originally approved a waiver of the requirements for informed consent for the BioTrust pertaining to specimens included in the specimen archive before the informed consent process was adopted.
  - Minimal risk research
  - No adverse affect on the rights and welfare of the subjects
  - Research could not practicably be carried out without the waiver
  - The subjects will be provided with additional pertinent information after participation

- The NPRM adds to those requirements

NPRM and Waiving Consent Requirements for Biospecimens

- Additional Requirements:
  - There are compelling scientific reasons to conduct the research; and
  - The research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained.

- Michigan reviews the waiver of informed consent approved for the Michigan BioTrust for Health on an annual basis and these new requirements will be added to that review.

Michigan BioTrust for Health

- Consent Statistics, January - April 2016
  - 86.6% of BioTrust consent forms returned completed
  - **67.4%** of newborns screened have BioTrust consent on record
  - 19.2% of newborns screened have BioTrust refusal on record
  - 13.4% of newborns screened have no BioTrust decision on record
    - Blood spots stored indefinitely, ***not*** used for research through BioTrust
- Consent versus screened populations, 2011-2014
  - 3.3% more white newborns
  - 3.6% less black newborns
  - Ethnicity and maternal age similar

Success is measured by the ability to make an informed decision

Thank You

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