

What are the risks if your baby's blood spots are used for research?

The risk is that your baby's blood spot could be identified. The chance this will happen is very low. Many steps are taken to protect privacy.

What steps are taken to protect privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. They are stored using a code and not your child's name. Details that could identify a child or family are removed. MDHHS has taken steps to keep blood spots secure. The highest level of protection, a "Certificate of Confidentiality" from the United States Department of Health and Human Services has been granted. Details are below:

Certificate of Confidentiality

US Department of Health and Human Services
<http://grants.nih.gov/grants/policy/coc/>

- It gives the BioTrust the right to refuse a court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The BioTrust will exercise that right.
- It cannot be used to resist a demand for information from personnel of the U.S. Government. It cannot be used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA.
- It does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give an insurer, employer, or other person your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Will you or your child benefit from blood spot research?

Most likely you or your child will not benefit. You will not be paid if your child's blood spots are used. Your family will not get money if products (such as new drugs) ever come from the research. You will help ensure the BioTrust represents all of the groups of people in our state. This ensures no group is left out of research. You, or a family member, may also be helped by research looking at new ways to diagnose, prevent or treat disease.

What are your choices for blood spot research?

You can say "yes" or "no" to blood spot research. You will be asked to check a box and sign a form found in your baby's newborn screening card. If you say "yes", all blood spots taken for newborn screening may be used, except for the blood spot saved for your own use if needed. If you say "no", blood spots will be stored but not used for research. You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

Can you change your mind?

Yes. You can call MDHHS at any time if you change your mind about blood spot research. After turning 18, your child must make this request.



What do you need to do?

ASK if you have questions.

VISIT www.michigan.gov/biotrust to read more about consent options.

CALL MDHHS if you still have questions about blood spots.

MARK your choice for blood spot research use on the BioTrust consent form and sign it.

GET your pink copy of the BioTrust consent form to take home.

MDHHS Newborn Screening Program

Telephone:
(Toll Free) 1-866-673-9939

Email:
newbornscreening@michigan.gov

Website:
www.michigan.gov/newbornscreening

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



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After Newborn Screening

Your Baby's Blood Spots



Learn More About the Facts and Choices You Need to Understand

Dear Parents:



Soon after birth a few drops of blood are taken from your baby's heel.

These "blood spots" are used for newborn screening. This program is required by state law and screens all babies for rare disorders to ensure early treatment. Please read "*Michigan Newborn Screening*" for more facts. Hospital staff or your midwife has a copy for you or visit www.michigan.gov/newbornscreening.

What happens to blood spots after newborn screening?

Often parts or whole blood spots end up not being used. Once newborn screening is done, the unused blood spots are stored forever. These stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. They are used to improve current tests or add more tests to newborn screening.

One blood spot is also kept by the state lab for your personal use, if needed. Parents have used this blood spot to help diagnose a disease in their child or to find reasons for a child's untimely death.

The rest of the blood spots are stored at a secure site, the Michigan Neonatal Biobank (www.mnbb.org). These stored blood spots may be used for research approved by the Michigan Department of Health and Human Services (MDHHS). The choice to allow this research is *yours* to make.

What is the Michigan BioTrust for Health?

The BioTrust is an MDHHS program created to oversee the research use of stored blood spots. One purpose of the BioTrust is to allow all groups of Michiganders to be part of research. Different groups help advise MDHHS on rules for research use of blood spots and suggest ways to inform the public. They include a Community Values Advisory Board with members from different organizations and the general public.



What type of research is done?

Blood spots can only be used for studies to better understand diseases or improve the public's health. We cannot predict every type of study that will be done. Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins. Studies have already:

- ◆ Looked for causes of cancer, birth defects and other health concerns, like obesity
- ◆ Improved newborn screening methods
- ◆ Tested mercury levels to find out if pregnant mothers are eating safe amounts of fish

For research guidelines and a list of studies visit
www.michigan.gov/biotrust

What are the steps for using blood spots in research?

1. MDHHS approves the study:

- BioTrust guidelines are met.
- Scientific Advisory Board(s) ensures the study is good science.
- Institutional Review Board(s) ensures subjects' rights are protected.

2. MDHHS selects blood spots:

- Blood spots are picked randomly, *or*
- Blood spots are picked because a researcher wants to study a specific group (such as people with cancer).

3. Researcher gets blood spots:

- Researchers are not told whose blood spot is provided.
- Data may be provided such as a diagnosis or year of birth.
- Information that can identify a person is not provided, unless that person is asked and consents.

4. Researcher performs study:

- Blood spots are studied.
- Results are recorded.
- Any left-over spots are destroyed.
- Study results are reported.

How many blood spots are stored and can be used for research?

Each year over 100,000 babies are born in Michigan. Almost all of these babies have newborn screening. All of these blood spots are stored in the Biobank.

Today, blood spots from over four million people are stored. If you or your child was born after July 1984, your blood spots are included. If collected before May 2010, these blood spots can be used for research unless you or your child (after age 18) contacts MDHHS. You may ask for your spots to be destroyed. You may also ask that your spots remain stored, but not used in research. Please call MDHHS for more details (Toll-free 1-866-673-9939).

Stored blood spots collected after April 2010 can only be used for research if a parent or legal representative returns a signed consent form allowing it.

Will you or your child get blood spot research results?

No. Personal research results are not provided. Researchers are not given data that can identify you or your child. This means, you cannot receive research results. A table listing all research using blood spots is posted at www.michigan.gov/biotrust. Research findings are posted here when studies are done.