

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

The risk is that your baby 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 coded only with a number and not your child's name or identifying information. Details that could identify a child or family are removed. MDHHS applies the highest level of protection to privacy available under the state public health code. The highest level of federal protection, a "Certificate of Confidentiality" was obtained from the United States Department of Health and Human Services. Details are below:

Certificate of Confidentiality

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

- The BioTrust can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The BioTrust can use the Certificate to resist any demands for information that would identify you, except as explained below.
- The Certificate cannot be used to resist a demand for information from personnel of the U.S. federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (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 an insurer, medical care provider, or other person obtains your written consent to receive research information, then the BioTrust will not use the Certificate to withhold that information.

Will you or your child benefit from blood spot research?

Blood spot research may not directly help you, your child, or your family. 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. This type of research usually aims to benefit communities by finding ways to improve the future health of many people. You, or a family member, may 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 included with your baby's newborn screening card. If you say "yes", blood spots left over from newborn screening may be used for research. If you say "no," blood spots will be stored and not used for research but may be used by the Newborn Screening Laboratory for quality assurance and quality control to improve newborn screening. You must contact MDHHS if you do not want left-over blood spots stored for any reason after newborn screening is done.

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.
- READ** more about consent options on the BioTrust website.
- 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.

Would you like to learn more?

Contact us by:

Telephone:

866-673-9939 (Toll Free)

Email:

BioTrust@Michigan.gov

Or visit:

Michigan.gov/BioTrust

For questions about your research rights, please call the MDHHS IRB at

517-241-1928



The Michigan Department of Health and Human Services will not exclude from participation in, deny benefits of, or discriminate against any individual or group because of race, sex, religion, age, national origin, color, height, weight, marital status, partisan considerations, or a disability or genetic information that is unrelated to the person's eligibility.

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 but serious disorders to ensure early treatment. To learn more, please read the *Michigan Newborn Screening* pamphlet or visit 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 for up to 100 years.

These stored blood spots may be used by the state lab to perform quality control tests and improve newborn screening. Blood spots can also be used for your personal use, if needed. Parents have used blood spots to help diagnose a disease in their child or to find reasons for a child's untimely death.

Your baby's blood spots will be stored at a secure site, the Michigan Neonatal Biobank (<https://mnb.wayne.edu/>). These stored blood spots may be used for research approved by MDHHS, with your written consent. The choice to allow this research is yours to make.

What is the Michigan BioTrust for Health?

The BioTrust is an MDHHS program that oversees the research use of stored blood spots. One purpose of the BioTrust is to allow all groups of Michiganders to play a part in research. The BioTrust Community Values Advisory Board has members from many organizations and the general public. It helps to advise MDHHS on rules for research use of blood spots and ways to inform the public. BioTrust Scientific Advisory Board members review each study for scientific merit.



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. Prior studies have:

- u Looked for causes of cancer, birth defects, and obesity.
- u Helped develop new newborn screening tests.
- u Tested mercury levels to find out if pregnant mothers are eating safe amounts of fish.

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 spots are 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 gives written consent.

4. Researcher performs study:

- Blood spots are studied.
- Results are recorded.
- Any left-over spots provided to the researcher 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 and have newborn screening.

Today, blood spots from over four million people are stored in the Biobank. If you or your child was born during or after January 1987, your blood spots may be 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 instruct MDHHS that your spots remain stored, but not used in research. Please contact MDHHS for more details (Toll-free 866-673-9939).

Stored blood spots collected after April 30, 2010 will not be used for research unless 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. MDHHS does not give researchers data that can identify you or your child. This means you cannot receive research results. A list of all research studies using Michigan blood spots is posted at Michigan.gov/BioTrust. Research findings are posted here when studies are done.