BioTrust for Health

How your baby's blood spots can be used in health research.

Learn more about your choices for blood spot storage and research participation.

Blood Spot Screening

A few drops of blood are taken from your baby's heel 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, visit Michigan.gov/NewbornScreening.

What happens to blood spots after newborn screening?

Often blood spots are left over after newborn screening. Current MDHHS policies state that blood spots will be stored at the Michigan Neonatal Biobank for 35 years and then destroyed. The Michigan Neonatal Biobank is located at Wayne State University.

While in storage, blood spots can be:

- Used to improve and test newborn screening processes.
- Returned for personal use, if requested by your family.
- Used, with your consent, for medical and public health research through the BioTrust for Health.

If newborn screening program needs change, storage may be extended to a maximum of 100 years. This brochure explains the BioTrust for Health program and your choices for participation. To learn more, visit Michigan.gov/BioTrust.

What is the Michigan BioTrust for Health?

The BioTrust is an MDHHS program overseeing use of stored blood spots for health research. The BioTrust consent form allows families to make a decision about participating in de-identified research.

De-identified research means that information that could identify you or your child is removed before blood spots are shared. For example, researchers do not receive names or birth dates. Blood spots shared with researchers are labeled with a de-identified code.

What type of research is done?

MDHHS only approves research that intends to better understand diseases or improve the public's health.

Prior research studies have:

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

Researchers may study a wide range of health topics, including ones not listed above.

What are the steps for using blood spots in research?

1. MDHHS approves the study.

Studies are only approved if participants' rights are protected, the quality of science is evaluated by experts and research teams agree not to use any methods that could identify someone and all research aligns with BioTrust policies.

2. MDHHS selects blood spots.

Blood spots may be picked at random to represent many different groups, or they may be selected to focus on one specific group, such as people with cancer.

3. Researcher gets blood spots.

Blood spots are shared with researchers using an anonymous code. The code allows MDHHS to link blood spots to some de-identified information, such as a diagnosis or year of birth. Researchers are legally restricted from trying to identify who blood spots belong to.

4. Researcher performs study.

Blood spots are used to study approved research topics. When the study ends, blood spots are destroyed. Study results are reported to MDHHS. To review a list of approved studies, visit Michigan.gov/BioTrust.

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 the BioTrust consent form around the time of your baby's newborn screening.

If you say “yes,” leftover blood spots may be used for approved research through the BioTrust.

If you say "no," blood spots will not be used for research through the BioTrust.

Your decision will not affect your baby’s newborn screening, only whether the stored, leftover blood spots can be used in future health research.

Can you change your mind?

Yes. You may contact MDHHS at any time to change your decision. You may direct that blood spots be made available for BioTrust research, stored but not used for research, returned to you, or destroyed. After turning 18, your child must make this request.

Blood spot storage and BioTrust consent practices have changed over time. Efforts to collect BioTrust consent from families began in May 2010. For people born before that date, their blood spots may be available for research through the BioTrust.

For more information, contact MDHHS at 866-673-9939 (toll-free).

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) result from the research.
- Personal research results are not provided because blood spots used for research are de-identified.

This type of research is done to improve the public’s health. Populations of people may benefit from research looking at new ways to diagnose, prevent or treat disease.

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

There is a very small risk your baby could be identified. Many steps are taken to protect privacy.

How can you learn more about the BioTrust for Health and your privacy?

Learn more about BioTrust consent options, approved research, and privacy protections at Michigan.gov/BioTrust.

What steps does MDHHS take to protect blood spots and information?

Your privacy is important. Blood spots and information are protected using de-identified codes, secure storage and strict rules about who can access them. The BioTrust takes additional steps to protect your privacy. Including:

- Double checking whether you consent to research before sharing blood spots.
- Ensuring studies meet BioTrust and Institutional Review Boards policies designed to protect your information.
- Sharing only de-identified blood spots and information with researchers.
- Confirming researchers destroy blood spots after the study ends.

Privacy and Confidentiality

The BioTrust is a medical research project. 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 also obtained from the U.S. Department of Health and Human Services.

The Certificate protects the privacy of research participants by prohibiting the BioTrust from sharing identifiable information to anyone not connected to the research except when the participant consents. There are limited exceptions to these confidentiality protections as required by law. For more details, visit Go.mi.gov/wb6cg2309.

What do you need to do?

- **ASK** your health care team if you have more 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 BioTrust consent form and sign it.
- **GET** your pink copy of the BioTrust consent form to take home.

To learn more, contact us at:

- Call: 866-673-9939 (toll-free)
- Email: BioTrust@michigan.gov
- Visit: Michigan.gov/BioTrust

For questions about your research, please call the MDHHS Institutional Review Board at 517-241-1928.

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