

BIOTRUST FREQUENTLY ASKED QUESTIONS

How Does the BioTrust Protect Your Privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. Blood spots are stored using a code and not a person's name. Details that could pinpoint a child or family are removed. The Department of Health and Human Services (MDHHS) has been granted the highest level of protection, a Certificate of Confidentiality from the United States Department of Health and Human Services.

Blood spots are separated from the newborn screening card and labeled with a storage code, then sent to the Michigan Neonatal Biobank for storage.



1

After newborn screening is completed, the filter paper containing left-over blood spots is separated from the newborn screening card that has the baby's directly identifiable information. A code is assigned to five remaining blood spots before transfer to the Michigan Neonatal Biobank for storage. The same code is applied to the sixth blood spot that remains in the State Lab for storage in case a parent or person (over 18 years) needs the spot. The Michigan Neonatal Biobank can not access and does not receive any directly identifiable information.

Requests for blood spots and data must be approved by MDHHS Institutional Review Board, BioTrust Scientific Advisory Board and MDHHS Programs.



2

Research requests are reviewed and approved by the MDHHS Institutional Review Board and Scientific Advisory Board to ensure protection of human subjects. Both boards must approve a study before blood spots are released. If a research study requires samples meeting certain criteria or asks for accompanying data, the MDHHS Program housing the data must approve its release. MDHHS will then conduct database linkages to select the right blood spots while still keeping blood spots and data confidential and coded.

Michigan Neonatal Biobank replaces storage code with a research code. Blood spots labeled with the research code given to researcher.



3

Once MDHHS identifies the blood spots and potential data required for an approved study, the Biobank receives a list of storage codes to retrieve blood spots for the study. Before the blood spots and potential coded data are released to a researcher the Biobank assigns another, different code. Thus, the code a researcher sees is two steps removed from the original newborn screening card number.

Researchers requesting identified blood spots or data must get consent from subjects for use in the specific study.

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What are Your Options?

For more details on your consent options please visit the "Consent" page on the BioTrust website.
(www.michigan.gov/biotrust)

Were you or your child born in Michigan before July 1984?

Blood spots received by the State Laboratory on infants born before July 1984 have been destroyed.

Were you or your child born in Michigan between July 1984 and May 1, 2010?

Today, blood spots from over four million people are stored. Blood spots collected between July 1984 and May 1, 2010, are coded and may be used in health research under a waiver of informed consent granted by the Michigan Department of Health and Human Services (MDHHS) Institutional Review Board. These blood spots may also be requested by a parent or person (>18y) for their own use. If you want to continue to allow the use of coded blood spots in health research, you do not need to do anything. If you do not want your or your child's blood spots made available for future health research you have two options to **opt-out**. You may fill out a form to: (1) request that blood spots remain stored but not used in future research, or (2) request that blood spots be destroyed. The lab requires verification that you are the legal representative entitled to make the request to destroy blood spots. You must submit your State ID or driver's license as well as a copy of your child's birth certificate.

RESIDUAL NEWBORN SCREENING BLOOD SPOT DIRECTIVE			
Michigan Department of Health and Human Services			
Child's Name at Birth	Date of Birth		
Child's Current Name	Check Birth Order if Multiple Birth <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd <input type="checkbox"/> 4 th <input type="checkbox"/> 5 th		
Mother's Name at Time of Child's Birth	Hospital of Birth		
I am a legal representative* of the child named above. I am asking the Michigan Department of Health and Human Services (MDHHS) to (check one)			
<input type="checkbox"/> Destroy all remaining blood spots. I understand that by checking this box, NO blood spots will be available for any future use including medical, identification, or research purposes.			
<input type="checkbox"/> Destroy only the portion of blood spots stored for research use. I understand by checking this box, one blood spot will be held by MDHHS. I must direct any potential future use including medical, identification or research purposes.			
<input type="checkbox"/> Store but not use blood spots for research after newborn screening is complete. I understand that the blood spots will be kept by the laboratory but not used for research of any kind unless directed in writing by me.			
*Legal representative means a parent or guardian of a minor who has authority to act on behalf of the minor or the individual from whom the specimen was collected if 18 years or older or legally emancipated.			
Signature of Parent, Guardian or other Legal Representatives		Relationship to Child	
Print Name		Date	
Street Address City		Zip Code	Phone Number
If you are asking MDHHS to destroy any blood spots, you must also attach a copy of the birth certificate belonging to the person whose blood spots are being destroyed AND the driver's license, state issued identification card or passport of the person who signed above.			
Return documents(s) via: Email: biotrust@michigan.gov Fax: 317-335-8419 or Post Mail: BioTrust Coordinator, NBS Follow-up Program, PO Box 30195, Lansing, MI 48909			
Please note that MDHHS cannot guarantee email security if you choose to submit this form and accompanying documents to the department via email!			
The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.			
Authority: Michigan Public Health Code, Act 368 of 1978			
MDHHS-5683 (Rev. 2-19)		1	

Was your child born in Michigan after April 30, 2010?

Blood spots from an infant born after April 30, 2010, will be stored for 100 years after newborn screening is done. However, the blood spots will not be used in research through the BioTrust unless a signed parental consent form is on file with the State Laboratory. New parents are given a BioTrust consent form to record whether "yes" they want blood spots made available for research or "no" they do not. One full blood spot will still be saved for future use by the child or family, should it ever be needed. *Please note, if a parent declines participation in the BioTrust, blood spots are still stored unless a form to destroy the blood spots is returned to the State Laboratory.*



Before signing this form please read, Your Baby's Blood Spots. It gives details on how small drops of blood (blood spots) collected for newborn screening may be used in research through the Michigan BioTrust for health. If you have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

Yes, my baby's leftover newborn screening blood spots may be used for health research.
By checking this box you understand:
• After newborn screening, blood spots are coded only with a number and stored up to 100 years at a secure site (BioBank). MDHHS can link the coded blood spots to your baby. This allows use of specific spots for research. It also allows MDHHS to find the right spots if you, or your grown child, change your mind.
• Researchers only receive coded blood spots. Details that could identify you, or your baby, are not provided.
• The risk of using blood spots in research is that your baby could still be identified. This risk is very low because many spots are taken to protect privacy.
• Research using blood spots must be approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health such as research on cancer, birth defects and diabetes.
• Many laboratory methods are used to study biological or environmental factors such as genes, infectious agents, toxins and metals.
• Blood spot research may not directly help you, your child or your family. This type of research aims to improve the health of communities.
• 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 leftover newborn screening blood spots may not be used for health research.
By checking this box you understand:
• Blood spots will be stored for up to 100 years but not used for research. The blood spots are stored so that the state lab can perform quality control tests and improve newborn screening.
• You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

Parent Signature _____ Date _____
Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information. For questions about your research rights or when to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-2838.

To make a personal choice about blood spot use, please contact the Michigan Department of Health and Human Services.

Call 1-866-673-9939 or Email biotrust@michigan.gov

www.michigan.gov/biotrust