



# Michigan BioTrust for Health:

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BioTrust Consent Training Module  
July 2022 Update  
*Michigan Department of Health and  
Human Services*



# Training Objectives:

The goal of this training module is to increase your understanding of.....



The Michigan BioTrust for Health program



Why blood spots are a unique resource for medical and public health research



Reasons for seeking consent for the use of blood spots in research



The role of providers in the BioTrust consent process



Resources available to assist in the consent process





## Residual Newborn Screening Dried Blood Spots

An added public health benefit from newborn screening (NBS)

Residual dried blood spots can be used...

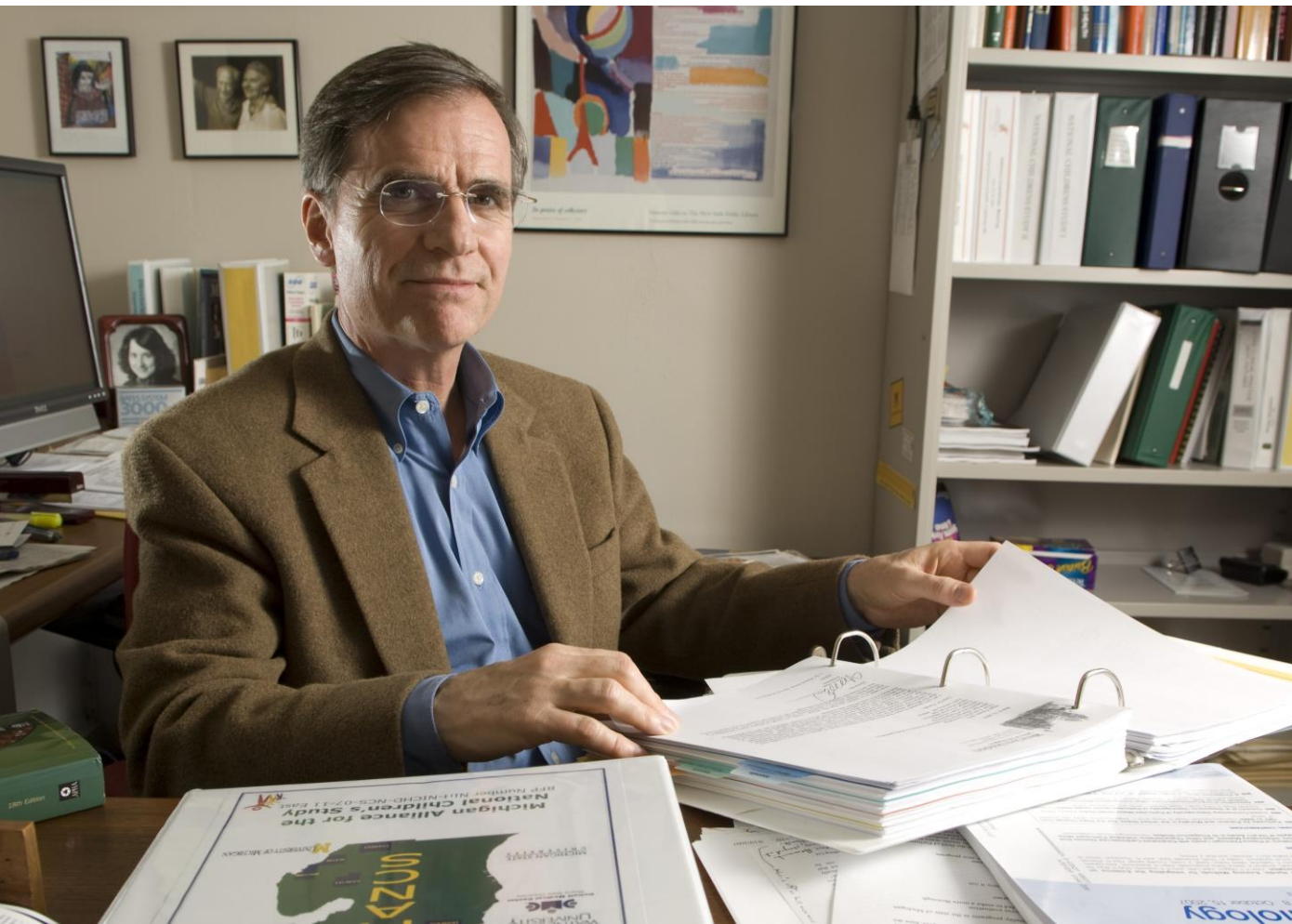
- To improve NBS
- For parental uses
- For medical and public health research



# Dried Blood Spots: An important resource for research

- More than 160 biomarkers can be measured on dried blood spots (DBS)
  - ✓ Proteins
  - ✓ Human DNA/RNA
  - ✓ Viral/bacterial DNA
  - ✓ Metals and other environmental toxins
- Can provide a snapshot of biological functions shortly after birth
- Potential to reduce disease burden in both children and adults
- DBS are collected on nearly all newborns and are an opportunity to conduct population-based research
- DBS may no longer be needed for clinical purposes
- Unique opportunity to link a biological sample to data routinely collected by state registries





“This leftover material is an invaluable pool of critical data. In the past few years, we’ve discovered, to many people’s surprise, that we can get very useful biological information from these tiny amounts of archived blood. Specifically, we can identify the expression of some genes just after the child’s birth, which is an indication of the biological challenges the baby was facing at that time. We think these ‘gene signatures’ may provide clues to the causes of developmental disorders influenced by events in pregnancy and the perinatal period.”



Dr. Nigel Paneth  
Pediatrician & Perinatal Epidemiologist  
Michigan State University

# What is the Michigan BioTrust for Health?



An MDHHS program that oversees the storage and research use of blood spots after newborn screening

The goals of the BioTrust are:

- To make blood spots from NBS more useful in medical and public health research
- To store blood spots to better preserve the samples
- To use blood spots in a manner acceptable to the public
- To inform the public and to allow personal decision making



# Why was the BioTrust launched?



Advances in technology make blood spots more useful than in the past



Increasing national and international interest in research using residual blood spots



To create a more transparent process for parents and the public



To invest in a storage facility equipped to optimally preserve the growing archive for many years to come



# Basis for Blood Spot Retention and Use

- Legal advice to retain residual blood spots for 21.5 years (1987)
- Michigan Commission on Genetic Privacy and Progress (1999)
  - “The commissioners believe that the NBS specimens represent a vital resource for the study and treatment of disease... because of their present and potential value, the commission recommends that NBS samples be retained indefinitely.”
- Public Health Code amended to direct MDHHS to develop retention schedule (2000)
  - “Allow the specimens to be used for medical research during the retention period... as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks”..
- MDHHS Laboratory policy revised for indefinite storage (2008)
- MDHHS Laboratory policy revised for storage up to 100 years (2017)





# What happens to DBS after NBS?



*Demo storage code label used and blurred to protect privacy.*

- 6 blood spots are collected to ensure that enough specimen is available to complete NBS
- Most specimens are normal and whole or parts of blood spots are left over
- The left over spots are labeled only with a code and sent to the Michigan Neonatal Biobank for long term storage



DEL  
STITUTE

HHS  
Human Services



URC

UNIVERSITY  
RESEARCH  
CORRIDOR



MICHIGAN STATE  
UNIVERSITY

**M** UNIVERSITY OF MICHIGAN

WAYNE STATE  
UNIVERSITY

# The Michigan Neonatal Biobank

Designated repository for Michigan blood spots



- Located at Wayne State University's TechTown Center of Excellence in Detroit
- 501c3 non-profit
- Increased privacy and security protections
- Improved temperature and humidity controls

# Michigan Blood Spot Archive



- ~4 million specimens dating back to 1987
- Annually over 100,000 specimens collected
- 2-3 million specimens processed, inventoried and transferred to the Michigan Neonatal Biobank



# What happens to DBS while in storage?

Many will never be used, but simply stored for possible future use. Here are examples of how DBS can be used while in storage:



Families may access the blood spots for their own personal uses (ex. additional clinical testing)



De-identified blood spots may be used quality improvement and assurance projects to improve newborn screening

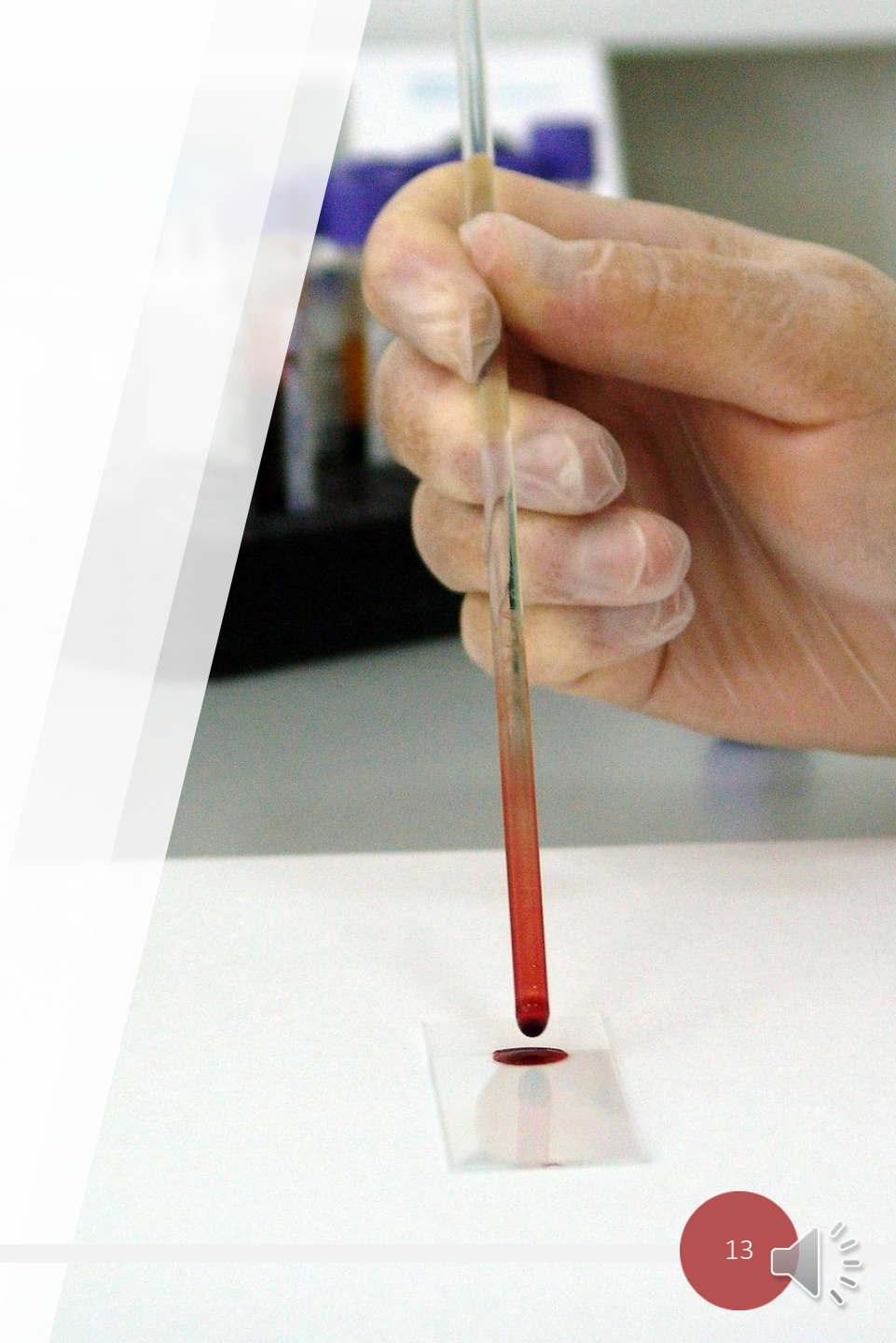


De-identified blood spots may be used in MDHHS approved medical and public health research through the *Michigan BioTrust for Health*



# What kind of research can use blood spots?

- Blood spots can be used in medical and public health research through the BioTrust
- Blood spots cannot be used for purely cosmetic or forensic research through the BioTrust
- Blood spots can only be used for identified research with additional study specific consent
- Blood spots can only be used for studies doing whole genome or exome sequencing with additional study specific consent
- Research policies and a list of studies using blood spots can be found at [www.Michigan.gov/BioTrust](http://www.Michigan.gov/BioTrust)



# How are DBS selected for research?



Research study is reviewed by MDHHS. Each study must be approved by both the MDHHS **Institutional Review Board** and the BioTrust **Scientific Advisory Board**.



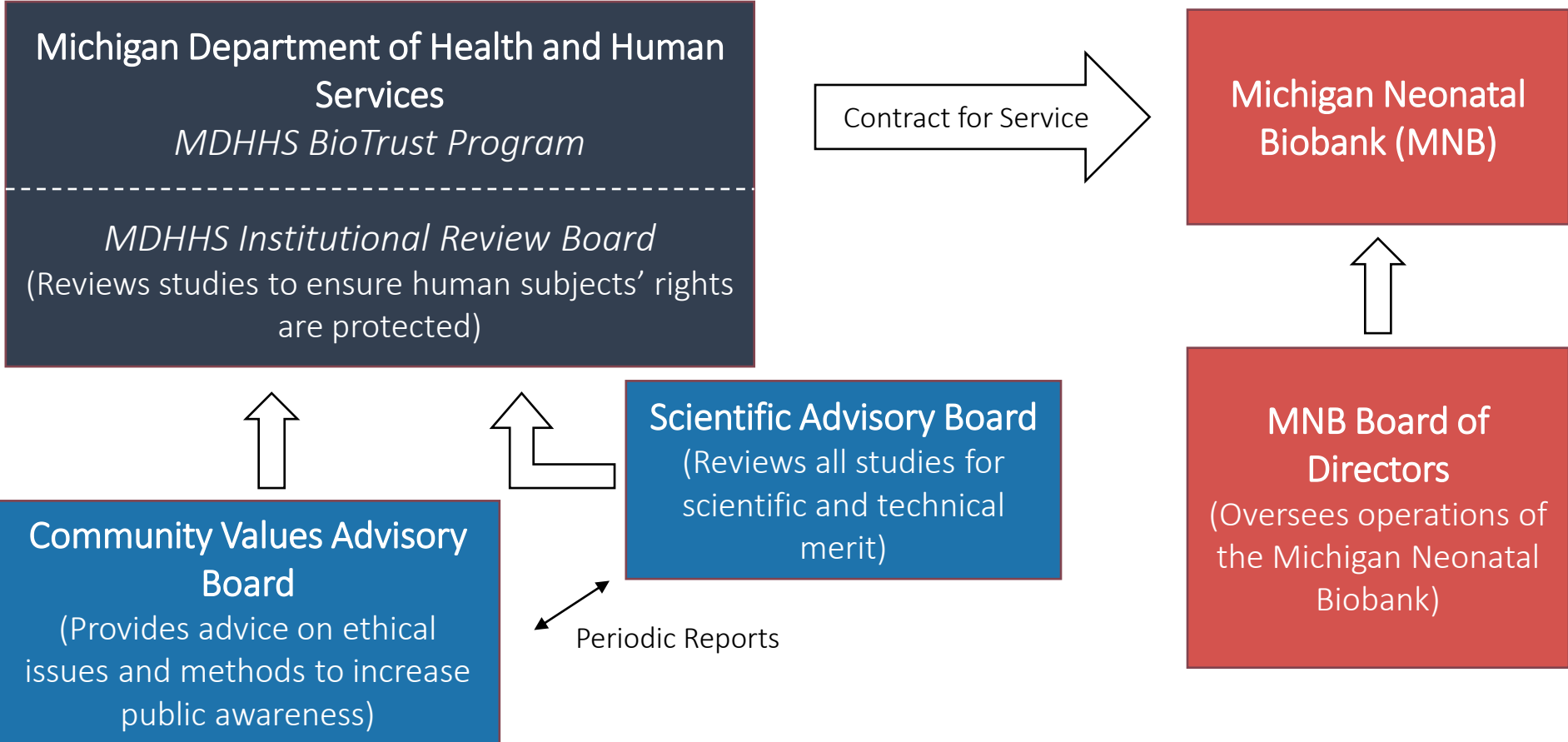
MDHHS selects blood spots based on the design of the research study. Researcher signs contracts with MDHHS and cost recovery fees are collected.



The Michigan Neonatal Biobank pulls, punches, and relabels blood spots for privacy. The Biobank collects cost recovery fees and sends DBS to the approved researcher.



# BioTrust Governance Structure



# Options for parents & young adults

## *"Opt-out" for blood spots collected prior to May 1, 2010*

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 <sup>st</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 3 <sup>rd</sup> <input type="checkbox"/> 4 <sup>th</sup> <input type="checkbox"/> 5 <sup>th</sup>	
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 document(s) via: Email: <a href="mailto:biotrust@michigan.gov">biotrust@michigan.gov</a> Fax: 517-335-9419 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 or expression, gender identity or expression, political beliefs or disability. Authority: Michigan Public Health Code, Act 368 of 1978			
MDHHS-5683 (Rev. 2-19) 1			

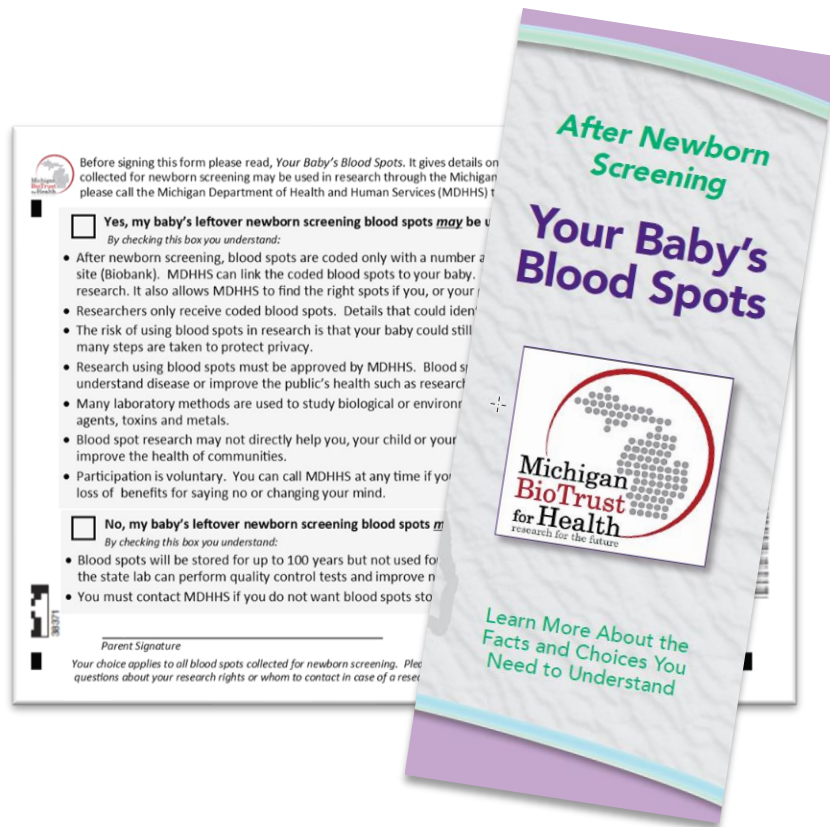
- Blood spots collected before May 1 of 2010 available for research through the BioTrust
- Available under a waiver of informed consent granted by the MDHHS IRB unless a person “opts out”
- Persons can “opt-out” by returning either a store only or destruction directive to MDHHS
- Directive form is available at:  
[www.Michigan.gov/BioTrust](http://www.Michigan.gov/BioTrust)





# Options for parents & young adults

## *"Opt-in" for blood spots collected on or after May 1, 2010*



- Statewide “Opt-In” consent process implemented for blood spots collected on or after May 1, 2010
- Blood spots only available for research if a “yes” consent form is on file with MDHHS





# BioTrust Consent Process Overview

The provider role in informing parents of their choices  
regarding the research use of residual DBS



# Why ask parents for consent?



Studies have shown public support crucial to success of biobanks worldwide



Focus groups and surveys in Michigan indicate that most parents support the idea of using blood spots in research, but they want to be asked permission



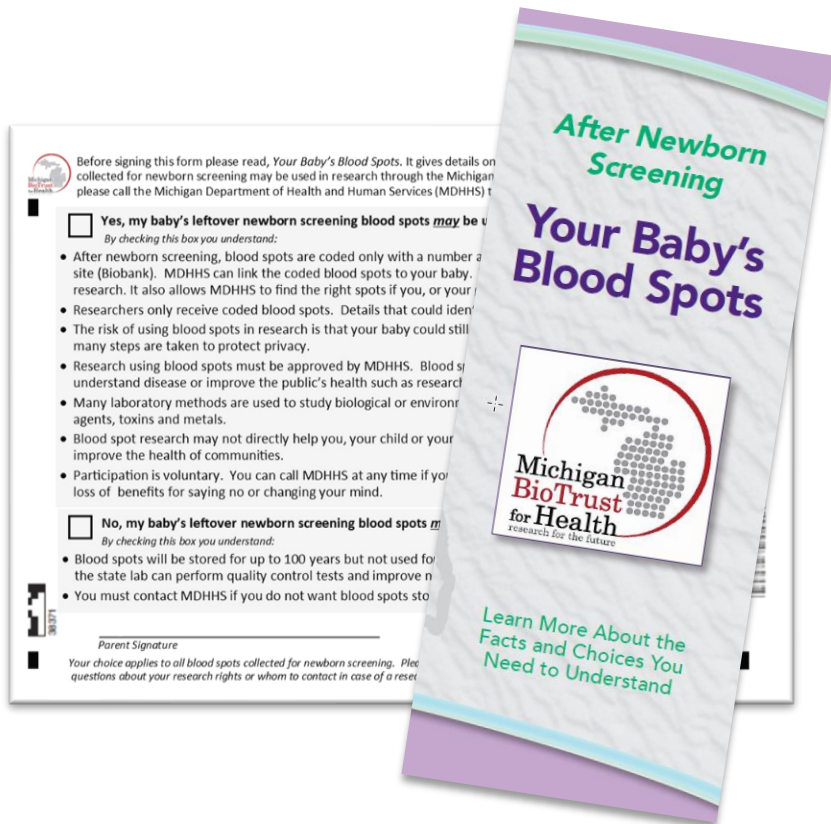
MDHHS Institutional Review Board identified the need for written consent for prospectively collected blood spots



Signature confirms that parent was given a choice whether or not to participate



# Consent Material Highlights



- BioTrust Consent Form
  - Less detailed than the brochure
  - 2-page carbonless copy attached to the back of the NBS card
  - Form where parents/legal guardian mark decision about the research use of left-over DBS
- BioTrust Consent Brochure
  - Ordered through the NBSO portal free of charge
  - Provides parents a detailed description of the BioTrust
  - Parents/legal guardians should read brochure before deciding

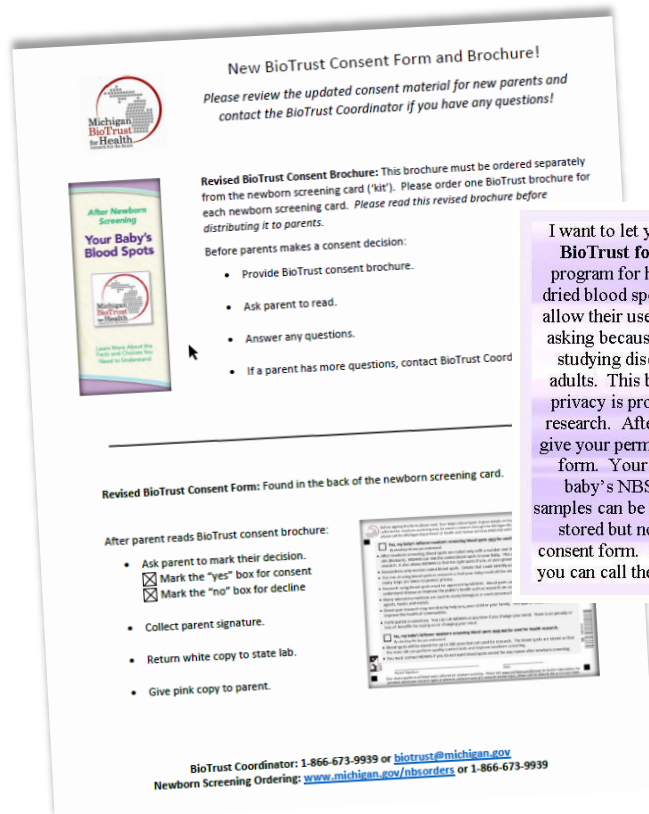


# What does the BioTrust consent cover?

- BioTrust consent is not consent for newborn screening. NBS is mandated by state law
- BioTrust consent is an opportunity for families to decide if blood spots leftover after newborn screening can be used in MDHHS approved research studies
- Covers only de-identified research, where researchers do not receive any details that could identify a person
- All blood spots will be stored for up to 100 years regardless of the decision on the BioTrust consent form
  - If family would like blood spots destroyed, they must contact the department and complete a directive form



# Materials to Support Staff



I want to let you know about the **Michigan BioTrust for Health**. The BioTrust is a program for health research using left over dried blood spots (DBS). It is your choice to allow their use for possible research. We are asking because DBS may be very helpful in studying diseases that affect children and adults. This booklet will explain how your privacy is protected when DBS are used in research. After reading this, if you'd like to give your permission, please sign this consent form. Your decision will not affect your baby's NBS— only whether the leftover samples can be used in the future. DBS will be stored but not used if you do not sign the consent form. If you do not want DBS stored, you can call the number on the NBS brochure.

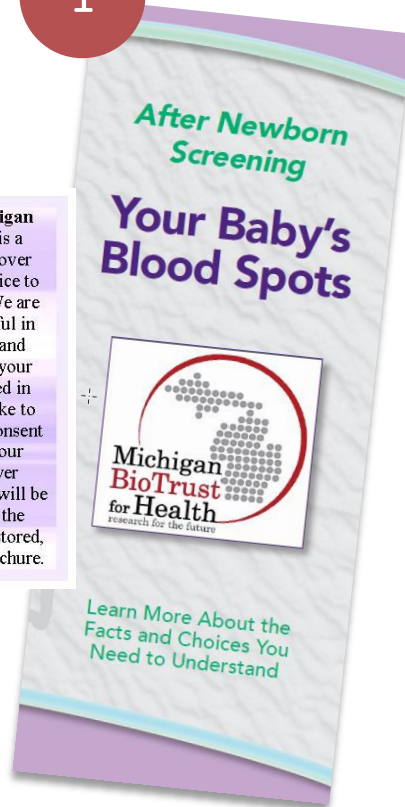
- BioTrust Pocket Script Cards
  - Used by staff to help introduce the BioTrust to new parents
- BioTrust Staff Instruction Sheet
  - Provides staff details on how to administer the BioTrust consent process to new parents



# Instructions for Hospitals

1

I want to let you know about the **Michigan BioTrust for Health**. The BioTrust is a program for health research using left over dried blood spots (DBS). It is your choice to allow their use for possible research. We are asking because DBS may be very helpful in studying diseases that affect children and adults. This booklet will explain how your privacy is protected when DBS are used in research. After reading this, if you'd like to give your permission, please sign this consent form. Your decision will not affect your baby's NBS— only whether the leftover samples can be used in the future. DBS will be stored but not used if you do not sign the consent form. If you do not want DBS stored, you can call the number on the NBS brochure.



## Step 1:

- Introduce the BioTrust to the parent(s) or legal guardian of the newborn using the pocket script card
- Provide BioTrust brochure to the parent(s) or legal guardian

***\*\*Contains required elements of consent\*\****



# Instructions for Hospitals

2

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 steps 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](http://www.michigan.gov/biotrust) for further information. 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

1901001

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 with consent form to MDHHS. Give parent one copy.

## Step 2:

- Confirm parent or legal guardian has read the BioTrust consent brochure
- Answer questions
- Hand parent or legal guardian the consent form for them to fill out





# Instructions for Hospitals

2

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.

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- Researchers only receive coded blood spots. Details that could identify you, or your baby, are not provided.
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**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](http://www.michigan.gov/biotrust) for further information. 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

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.

## Step 2 continued:

- Ask parent or legal guardian to complete the consent form
- A completed form includes:
  - ✓ One box clearly checked
    - “Yes” means DBS could be used for research
    - “No” means DBS will be stored but not used for research
  - ✓ Signature of parent/legal guardian
- Staff should never sign on behalf of family. Only a parent or legal guardian can complete the form.



# Instructions for Hospitals

2

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.

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*By checking this box you understand:*

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**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](http://www.michigan.gov/biotrust) for further information. 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

1901001

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 with consent form to BioTrust. Give parent one copy.

## Step 2 continued:

- Top “white” copy gets returned to the state NBS lab via the courier
- Bottom “pink” copy is given to the parent(s) to take home for their records



# Instructions for Hospitals

- *Do not delay shipment of blood spots while waiting for parental decision about the BioTrust*
- Completed consent forms can be returned to the state lab via the courier in a separate envelope that the newborn's blood spot
- The consent form has the NBS kit number printed on it and will be linked to the blood spots by the MDHHS lab



# Are there times when you should not collect the consent decision?

**YES!** Do not collect the decision if:



Mom or baby's health is in jeopardy




You cannot determine the child's legal representative

*Please contact us if you have questions about specific consent situations!!*



# Alternate Consent Form

Michigan Department of Health and Human Services

 **BioTrust Alternate Parental Consent Form: Newborn Screening Blood Spot Research Use**

Child's Name at Birth:	Date of Birth:
Newborn Screening Kit Number:	Circle Birth Order if Multiple Birth: 1st 2nd 3rd 4th 5th
Mother's Name at Time of Child's Birth:	Hospital of Birth:

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 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.
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**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.

Your choice applies to all blood spots collected for newborn screening. Please visit [www.michigan.gov/biotrust](http://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.

\_\_\_\_\_  
Parent Signature

\_\_\_\_\_  
Date

Return document(s) via:  
Email: [biotrust@michigan.gov](mailto:biotrust@michigan.gov) Fax: 517-335-9419 or  
Post Mail: BioTrust Coordinator, NBS Follow-up Program, PO Box 30195, Lansing, MI 48909

<small>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.</small>	<small>Authority: Michigan Public Health Code, Act 368 or 1978</small>
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- An alternate version of the BioTrust consent form is available at [www.Michigan.gov/BioTrust](http://www.Michigan.gov/BioTrust)
- This form can be used if the original consent attached to the NBS card is lost or unable to be used for some other reason
- If using this form, make a copy of the signed document for the family to take home
- Alternate consents can be returned to the state lab via the courier



# Resources for Families

- General Program Info: [www.Michigan.gov/BioTrust](http://www.Michigan.gov/BioTrust)
- BioTrust brochure
  - [English](#), [Spanish](#), [Arabic](#), [Audio Recording](#)
- BioTrust Roadmap (ideal for prenatal education)
  - [English](#), [Spanish](#), [Arabic](#)
- [BioTrust FAQ Documents](#)
- Video about the Michigan BioTrust for Health and Consent Options (<https://youtu.be/AJaZP0wtqqI>)
- Directive to Destroy/Store Blood Spots
  - [English](#), [Spanish](#), [Arabic](#)



# Resources for Staff:

- General Program Info: [www.Michigan.gov/BioTrust](http://www.Michigan.gov/BioTrust)
- Resources for Hospitals & Health Professionals: [https://www.michigan.gov/mdhhs/0,5885,7-339-73971\\_4911\\_4916-233593--,00.html](https://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916-233593--,00.html)
- Pocket script
- Direct Links:
  - [Hospital Instruction Sheet](#)
  - [Alternate BioTrust Consent Form](#)
  - Directive to Destroy/Store
    - [English](#), [Spanish](#), [Arabic](#)



# Key Points to Remember



- Typically, some blood spots are left over after newborn screening is complete
- State law in Michigan allows residual de-identified blood spots to be used in medical research as long as human subjects' rights are protected
- All research studies are de-identified, where the researcher does not know whose blood spots are being used, unless a family is contacted and asked for specific permissions



- Blood spots collected in Michigan prior to May 1, 2010, are available for research unless a parent or individual opts out by contacting MDHHS
- Blood spots collected in Michigan after April 30, 2010, are only available for research if a parent or legal guardian grants consent for the BioTrust or for a specific study
- The BioTrust consent only asks for permission to use left over blood spots in research and is NOT consent for newborn screening or storage of blood spots
- Parents or individuals can change their mind or request that blood spots be destroyed by contacting MDHHS





# Key Points to Remember



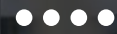
- Ensure parent(s)/legal guardian receive the BioTrust consent brochure
  - Ask parent(s)/legal guardian to read the brochure prior to making a decision about the BioTrust
  - Ensure parent(s) or legal guardian mark their decision and sign the BioTrust consent form
  - Return the white copy of the consent form to the state NBS laboratory
  - Provide parent or legal guardian with the pink copy of the BioTrust consent form
- 



- FAQ documents are available on the BioTrust webpage to assist in answering parent(s) questions about the BioTrust
- BioTrust educational pieces designed for prenatal education are available if parents visit the hospital prior to delivery and can help families be more prepared to make a consent decision
- If families have questions beyond the scope of the brochure or educational materials on the webpage, they can contact MDHHS directly using the contact information on the back of the brochure



# THANK YOU



Shelby Atkinson



517-335-6497



atkinsons2@michigan.gov



[www.Michigan.gov/biotrust](http://www.Michigan.gov/biotrust)

