



# BioTrust Staff Instruction Sheet

**Purpose:** To provide guidance to staff involved in collecting consent decisions from new families shortly after birth on the Michigan BioTrust for Health Consent Form. This 2-step process can only be completed with a parent or legal representative of the newborn and staff should be present throughout.

## Step 1: BioTrust Consent Brochure

The BioTrust brochure contains detailed information for families to consider when making a decision about the research use of blood spots left over after newborn screening. This brochure must be ordered separately from the newborn screening card (kit). Please order one BioTrust brochure for each newborn screening card and read through it before distributing it to parents.

Before a parent makes a consent decision:



- Provide the BioTrust consent brochure
- Ask parent to read
  - Alternate languages and audio version of brochure available at [Michigan.gov/BioTrust](http://Michigan.gov/BioTrust)
- Answer any questions.
  - Direct parents to [Michigan.gov/BioTrust](http://Michigan.gov/BioTrust) for access to frequently asked questions (FAQs) and more information about the BioTrust program
- If a parent has more questions, contact the BioTrust Coordinator

## Step 2: BioTrust Consent Form

The BioTrust consent form is attached to the back of each newborn screening card. This form is where families mark a decision about the research use of their child's blood spots left over after newborn screening. This form can only be completed by the parent or legal representative; no one can complete this form on behalf of the family.

- Ask parent to mark their decision
  - Mark the "yes" box for consent
  - Mark the "no" box for decline
- Collect parent signature on the form
- Return white copy to state lab via the courier
- Give pink copy to parent to take home

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

BioTrust Coordinator: 517-335-4181 or [BioTrust@michigan.gov](mailto:BioTrust@michigan.gov)  
Newborn Screening Ordering: [Michigan.gov/NBSOrders](http://Michigan.gov/NBSOrders) or 517-335-1400