



# Newborn Screening and BioTrust

## Frequently Asked Questions



### **Why is Newborn Screening (NBS) important to Public Health?**

Each year around four million babies are born in the United States. Some of these babies are born with conditions which, left untreated, can rapidly result in death or permanent disability. NBS can catch some of these disorders in time for them to be effectively treated. NBS is so beneficial to public health that all 50 states, Washington D.C., and Puerto Rico have implemented screening programs.

Nationwide, NBS saves or improves the lives of about 12,000 babies annually. Every year, Michigan's NBS program, administered by the Michigan Department of Health and Human Services (MDHHS), identifies approximately 250-280 babies afflicted by one of the 54 blood-spot-testable disorders included on the NBS panel. Of the 111,725 Michigan babies screened in 2015, 270 were diagnosed with one of these disorders, a rate of about one in every 414 babies.

### **Does NBS require parental consent?**

No. Under Michigan Law (MCL 333.5431), parental consent is not required to perform NBS. This is in recognition of the tremendous public health value of NBS.

### **Where is NBS performed?**

NBS is performed at the MDHHS Laboratory in Lansing. MCL 333.5431(2) permits the Department to require that NBS be performed in the state laboratory. Centralizing screening in one location improves the quality, efficiency, and accuracy of the NBS program, better protecting Michigan's babies.

### **What happens to residual dried blood spots after NBS?**

One of the dried blood spots is de-identified, assigned an anonymous numeric code, and securely stored at the MDHHS Laboratory for parental use, if needed (e.g., future disease diagnosis).

The other dried blood spots are likewise de-identified, assigned the same anonymous numeric code, and stored at a secure site. MDHHS contracts with Wayne State University (WSU) to store these spots. WSU in turn subcontracts with a non-profit charitable organization, the Michigan Neonatal Biobank, to store the spots in a climate-controlled specimen management facility.

As part of the NBS process, some of the residual dried blood spots are used by the MDHHS Laboratory for NBS quality assurance, test improvement, and test development. This helps to ensure accurate and timely screening for other babies.

As described below, dried blood spots can also be used for de-identified medical research and crime victim identification.

## **How are dried blood spots made available for research?**

Dried blood spots are valuable for public health research because they provide information about environmental and biological factors that can affect human health. MDHHS created the Michigan BioTrust for Health, a program designed to oversee and facilitate researcher access to dried blood spots following careful review of each proposed study. At MDHHS's direction, the Biobank makes de-identified dried blood spots available to public health researchers.

Michigan was the first state to secure consent from all new parents for de-identified medical research using NBS dried blood spots. Beginning on May 1, 2010, hospitals and midwives began providing a consent form to new parents. Parents are empowered to choose whether or not they want their baby's residual dried blood spots to be used for de-identified medical research benefitting public health. Spots collected prior to May 1, 2010, can be used for de-identified medical research unless a parent submits a request to mark their child's spots as unavailable for research. Adults can make this request on their own behalf.

Parents who do not want their child's spots to be kept by MDHHS can submit a request to have those spots destroyed. Adults can make this request on their own behalf.

## **Who reviews requests from researchers for de-identified dried blood spot research?**

Research requests to use de-identified blood spots are submitted to the BioTrust, where they undergo multiple levels of review by the Bureau of Laboratories, Bureau of Epidemiology and Population Health, the MDHHS Institutional Review Board, and a panel of three Scientific Advisory Board members. The review process ensures that the proposed research study has scientific merit; that the research complies with departmental policy; that the researchers are qualified to conduct the research; and that human subjects and data are protected.

## **Why is de-identified dried blood spot research important?**

Research performed using Michigan dried blood spots has helped improve NBS techniques. For example, use of dried blood spots through the BioTrust has been instrumental in developing NBS tests for the debilitating disorders Spinal Muscular Atrophy and Niemann-Pick C Disease. Research facilitated by the BioTrust has also contributed to advancements in the study of cancers and environmental exposure. A summary of approved studies is available on MDHHS's website.

## **Are dried blood spots sold to anyone?**

No. The Biobank charges a small administrative fee to fulfill researcher requests for de-identified dried blood spots in MDHHS-approved research projects, but not for the blood spot itself. The fee helps offset the cost of storage, labor, and shipping. Neither the Biobank nor MDHHS receives a profit from the BioTrust program.

## **How does MDHHS protect privacy?**

The NBS process and storage of dried blood spots includes many layers of security to protect the dried blood spots. Only authorized employees are permitted to access the dried blood spots. The facilities which store dried blood spots are well secured. Stored dried blood spots are deidentified.

Researchers are only provided dried blood spots in a deidentified form. This means researchers don't know whose blood spots they are using. The only exception is if you specifically grant permission to a researcher to use your dried blood spots in an identified form.

The dried blood spots are also protected under the law - MDHHS is only permitted to use dried blood spots for quality improvement and test development of NBS disorders, parent- or guardian-directed medical research, crime victim identification, and de-identified medical research.

### **Does MDHHS ever provide a dried blood spot to law enforcement?**

MDHHS will only provide a dried blood spot to law enforcement for the purpose of crime victim identification. Most of the time, this means someone has been killed or gone missing.

The Department will only release a dried blood spot to law enforcement if: 1) approval is granted by a family member authorized to act on the crime victim's behalf, or 2) law enforcement obtain a valid judicial warrant or subpoena which clearly states that the dried blood spot will be used for crime victim identification only.

MDHHS rigorously follows its policy of providing a dried blood spot to law enforcement only for the purpose of crime victim identification.

*To learn more, please reach us by telephone (toll free 1-866-673-9939) or email ([newbornscreening@michigan.gov](mailto:newbornscreening@michigan.gov) for questions about newborn screening or [biotrust@michigan.gov](mailto:biotrust@michigan.gov) for questions about the BioTrust for Health).*