



## Parental Consent for Research Use of Newborn Screening Blood Spots and Test Results

### **COMPLETE THIS FORM ONLY IF YOUR CHILD'S NEWBORN SCREENING BLOOD SPOTS WERE COLLECTED ON OR AFTER 8/1/2014**

Newborn Screening is a program that screens all babies at birth for serious health conditions.

When your baby is 24 to 48 hours old (in most cases), a few drops of blood are taken from your baby's heel by hospital staff. The drops of blood are used to fill five spots on a filter paper card. The card is then sent to the Minnesota Department of Health (MDH) Newborn Screening Program laboratory for testing. Newborn Screening tests for over 50 conditions that can cause illness, disability, or death if not treated right away.

#### **Why does MDH store and use Newborn Screening blood spots and test results?**

Newborn screening blood spots and test results may be used to help your family or other families in Minnesota. When MDH stores your child's blood spots and test results, they will be available to you in the future for further health-related testing of your child. Blood spots can also be used for identification purposes in the case of a missing or deceased child. Additionally, newborn screening blood spots can be used to develop new or improved newborn screening tests and for population-based research. Newborn screening blood spots often represent the entire state, so they can help to provide better understanding of the public and personal health issues affecting Minnesota residents.

#### **How can dried blood spots be used for research?**

Dried blood spots contain a variety of biological markers that can be helpful in studying causes of birth defects, childhood cancer, or chronic disease. Biomarkers found in dried blood spots include elements like antibodies, deoxyribonucleic acid (DNA), environmental toxins, and proteins. It is not possible or permissible to use dried blood spots for cloning or stem cell research.

#### **Will my baby's blood spots or test results be personally identifiable?**

All of your child's dried blood spots and test results are stored by MDH with identifying information attached. However, public health research use of the spots or results will only be allowed as long as privacy of the child is maintained. Privacy is maintained by separating identifying information from the blood spots. All directly identifiable information (name, address, birthdate, etc.) about the child will be removed so researchers won't know whose blood spot is being used. Because of this, it is unlikely that personal results from research studies would be given to you.

## What are the benefits to using Newborn Screening blood spots and test results?

Allowing the blood spots and test results to be used for research may not have an immediate benefit to your family, but your family and other families may be helped later on by research that develops new ways to diagnose, prevent, or treat disease. In fact, past research has allowed Newborn Screening to grow so the program is able to help significantly more babies today than it did 40 years ago.

## What are the risks of using my child's Newborn Screening blood spots or test results for research?

Your child's blood spots or test results could be identified. The chance this would happen, however, is extremely small because of the steps taken to protect privacy.

## Who else might have access to my baby's Newborn Screening blood spots or test results?

Access to blood spots or test results will be granted only to researchers whose public health studies are approved by an ethics committee called an Institutional Review Board (IRB). An IRB assures the protection of all individuals in research projects. Research using Newborn Screening blood spots or test results will need to be approved by both the MDH IRB and the researcher's institutional IRB. Access to Newborn Screening blood spots or test results will not be granted to law enforcement, insurance companies, or others unless required by law or a court order.

## Can I change my mind?

Yes. You can contact MDH at any time to revoke your approval for storage and use of your child's blood spots or test results. MDH will ask you to sign and date a form indicating you no longer want your child's blood spots or test results stored. After the Newborn Screening blood spots or test results are destroyed, MDH will notify you of the destruction and the date of destruction.

***By signing this form, I consent to allow MDH to use any of my child's blood spots and test results for public health studies or research not necessarily related to newborn screening and to disseminate the blood spots and test results to external research entities as long as needed to accomplish the public health studies or research. I understand that this consent is for an indefinite period and that I may revoke it at any time.***

Name of infant:	Birth date:
Hospital or Place of birth:	

Parent or guardian signature: \_\_\_\_\_

Parent or guardian printed name: \_\_\_\_\_

Relationship to child: \_\_\_\_\_ Date: \_\_\_\_\_

Street address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_



## **Parental Consent for MDH to Use Newborn Screening Blood Spots and Test Results**

*Attached Tennessee Warning, under Minnesota Statutes Section 13.04, subdivision 2:*

- (a) If you provide consent, the Minnesota Department of Health (MDH) may use any of your child's blood spots and test results for the following: (1) for possible use by you or your health care provider for future health-related testing or identification of your child in the case of a missing or deceased child, and (2) for public health research.
- (b) Providing consent to use your baby's blood spots and test results is voluntary. You may choose to consent or not to consent. You do not have to do or sign anything if you do not want to give MDH consent.
- (c) If you give your consent, MDH may use all of your baby's blood spots and test results. If you give consent now, you may revoke it later if you change your mind.
- (d) Access to Newborn Screening blood spots or test results will be granted only to external researchers whose public health studies or research projects are approved by the MDH Institutional Review Board. Access to Newborn Screening blood spots or test results will not be granted to law enforcement, insurance companies, or others unless required by law or a court order.