



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

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

When your baby is 24 to 48 hours old, 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. If stored, your child's blood spots and test results 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.

What are dried blood spots and what will be retained by MDH?

Newborn screening blood samples are collected on a filter paper card and dried before being sent to the laboratory. This is why newborn screening samples are often called 'dried blood spots.' After newborn screening is done, a small amount of this dried blood is left over. This leftover dried blood is what will be stored.

What test results will be stored?

Newborn screening tests for over 50 disorders. The results of this testing (the actual lab values and whether the test was positive or negative) will be stored.

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?

Your child's dried blood spots and test results will be 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 storing and using Newborn Screening blood spots and test results?

Storing your baby's blood spots and test results will help ensure they are available to you or your healthcare providers for further health-related testing or for identification purposes in the case of a missing or deceased child. 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 to storing my child's Newborn Screening blood spots or test results?

The only risk is that 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.

How long will my baby's Newborn Screening blood spots and test results be stored?

If you choose to allow MDH to store your baby's Newborn Screening blood spots and test results, they will be stored by MDH for no longer than 18 years from your baby's date of birth.

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 understand that I am choosing to allow my child's blood spots and test results to be retained by MDH for a period of no longer than 18 years from my child's date of birth or until I request otherwise.

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: _____ Zip: _____



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Attached Tennessen Warning, under Minnesota Statutes Section 13.04, subdivision 2:

- (a) If you provide consent, the Minnesota Department of Health (MDH) will store your baby's Newborn Screening blood spots and test results. The blood spots and test results may be used for the following: (1) to improve the Newborn Screening Program by developing better or new tests, (2) 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 (3) for public health research.
- (b) Providing consent to store and 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 will store your baby's blood spots and test results and may use them as described in (a), above. If you do not give consent, your child's blood spots and test results will be destroyed and will not be available to you or your child's health provider at a later time. 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.