

What is newborn screening?

Newborn screening is a special test that helps identify babies who are at risk for certain conditions. A newborn baby may look healthy, but can have a serious condition that cannot be seen. These conditions can be treated if found early. Indiana state law requires that all babies in Indiana be tested for 49 conditions, including hearing loss and critical congenital heart disease (also called CCHD).

What is a dried blood spot?

Before every baby goes home from the nursery, he/she has a small amount of blood taken from his/her heel. The baby's blood is collected in five circles on the newborn screening card. This is called a **heel-stick or dried blood spot** (also called **DBS**) **sample**. The DBS is used to test for a specific group of conditions. Small pieces of the DBS are punched out and used to perform the newborn screen. Sometimes, the newborn screening laboratory may repeat (or double-check) a baby's test by using the extra spots from the DBS. Often, one or two of the five circles collected on the DBS will not be used.

Why are dried blood spots kept?

There are several reasons why dried blood spots are kept. First, good laboratory practices require that samples (such as DBS) be kept for a period of time after testing is done, in case a test needs to be checked or repeated. DBS are also used by Indiana's newborn screening laboratory to help develop new tests for newborn screening and to make sure that laboratory equipment is working correctly.

Are DBS used for anything else after newborn screening?

Indiana's newborn screening law allows leftover DBS to be used for medical research after newborn screening is completed. It is also possible that a child's parent(s) or guardian(s) may request that his/her/their child's DBS be used to help investigate a crime, such as a missing child. *It is important for parents to know that your child's DBS will be destroyed no more than 3 years after he/she is born, even if you agree to allow your child's DBS to be used for medical research.*

What types of medical research could be done using DBS?

Dried blood spots contain information (including genetic information) that may be useful for studying birth defects and diseases. DBS might also be used to evaluate the effects certain infections or substances (such as lead) have on a developing baby.

Why do researchers want to use DBS?

Using DBS for medical research can provide important information about what may cause a disease or impact a person's health—not just in Indiana, but all over the world. Since a baby's entire DBS may not be used, there can be hundreds or thousands of DBS available for medical research at any time. Studying samples from a large group of people at the same time means that researchers will be able to perform high-quality studies and have a higher chance of making an important new discovery. Also, using a large number of samples may lower the cost of performing a research study.

How many dried blood spots are available for medical research?

Every year, approximately 85,000 babies are born in Indiana. Starting in 2013, each baby's parent(s) or legal guardian(s) will be asked to decide whether he/she/they want to allow the child's DBS to be available for use in medical research. *Newborn screening dried blood spots that were collected before parents/guardians were asked to decide whether a child's DBS could be used for medical research are NOT available for use in research.*

How does the Indiana State Department of Health (ISDH) Genomics & Newborn Screening Program decide that a researcher can have access to DBS?

Every researcher, company, or organization that wants to use dried blood spots from Indiana will have to submit a written request to the ISDH Genomics & Newborn Screening Program. Each request must give ISDH details about the

research project, including:

- The reason why a researcher/company/organization is asking for access to Indiana's dried blood spots,
- The information that will be learned by studying Indiana's dried blood spots,
- The total number of dried blood spots being requested, and
- Plans for publishing any results of the research study.

Each research request is reviewed by the ISDH Genomics & Newborn Screening Program and other members of ISDH. The requests are reviewed to make sure that Indiana's dried blood spots will only be used by people/companies/organizations for research studies that could provide valuable medical information.

How are DBS selected for a medical research study?

If a research request is approved by the ISDH, the next step is choosing the DBS that will be used in the research study. The way that DBS are chosen depends on the request made by the person(s) performing the study. Sometimes, a researcher will only ask for a certain number of samples (such as 100). In these cases, the DBS will be selected at random. Other researchers may ask for a specific group of DBS, such as DBS from children born in a certain year.

What information about my child would be given to a person/company/organization doing medical research?

None. Indiana's newborn screening law does not allow researchers to have access to any identifying information about your child (such as your child's name or address). Researchers will only be given a punch from your child's DBS. No other identifying information (such as your child's name or address) will be shared. No identifying information about you or your child will be published or available to anyone else.

Would I/my child get any medical information (such as test results) from a researcher?

No. If your child's DBS is used in a research study, the researcher will not receive any information that will identify you or your child. As a result, you or your child would not receive any medical information (including test results) from the researcher.

Do I have to agree to allow my child's DBS to be used for medical research?

No! It is important for parents/guardians to know that you don't have to allow your child's DBS to be used for medical research. The choice is yours.

If I agree to have my child's DBS used for medical research now, can I change my mind later?

Yes. If you agree to have your child's DBS used for medical research, you can change your mind at any time. If you change your mind later, please call the ISDH Genomics & Newborn Screening Program at (888) 815-0006.

What if I don't want my child's DBS used for medical research after newborn screening is done?

That's okay! Check the box on your child's heel-stick card that says "NO." Your child's DBS will be kept for 6 months (in case a newborn screening test needs to be repeated) and then destroyed. Your child's DBS will *NOT* be available for use in any research.

Where can I find more information?

If you have more questions, or would like more information, please contact the ISDH Genomics & Newborn Screening Program at (888) 815-0006 or www.nbs.in.gov.



Indiana State
Department of Health

Genomics & Newborn
Screening Program

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