



What is the Newborn Screening (NBS) Program?

The Newborn Screening Program is a public health program that screens all babies for many serious diseases. California has a law that requires that all babies be screened for 80 different diseases. If not found and treated early, many of the diseases can cause serious and permanent health problems, severe developmental delay and even death.

Each year, about 750 California babies (1 in about every 650 births) are found to have one of the diseases. Since its start in 1966, more than 14,000 California babies have been found and treated as a result of NBS.

How is NBS done?

When a baby is a day or two old, before the baby is discharged from the hospital, a few drops of blood are taken from the baby's heel. These drops are used to fill approximately six small spots on a filter paper card. These spots are usually called "dried blood spots" (DBS) because the circles of blood are dried before being sent to a regional laboratory for testing. The pamphlet, [Important Information for Parents about the Newborn Screening Test](#), explains newborn screening. Ask your doctor, hospital staff or your midwife for a copy. You can also find it on our website:

<http://www.cdph.ca.gov/programs/nbs/Pages/NBSEducationMaterial.aspx>.

What happens to the blood spots?

Small punches from several of the blood spots are used for newborn screening laboratory testing. All six spots are usually collected in case additional punches are needed to complete testing. After newborn screening is completed, what is left of the blood spots is stored indefinitely in a secure freezer storage facility, the California Biobank. Filter paper cards are labeled with a unique bar code number and have no other identifying information on them.

What are leftover blood spots used for?

The NBS Program uses the remaining blood spots to evaluate and improve current screening tests, develop and evaluate new screening tests, and develop and evaluate treatments.

Over the last 20 years, newborn screening in California has gone from testing each baby for 3 diseases to testing for 80 diseases, including cystic fibrosis and severe combined immunodeficiency (SCID), commonly known as "bubble boy" disease. Because of this, we have been able to prevent serious illness, including death and disability, in many more babies.

What kind of research has already been done using blood spots?

Past research has included studies on autism, childhood leukemia and lymphomas as well as development of newborn screening tests for many metabolic disorders and SCID.



What does the California Biobank Program (CBP) do?

The California Biobank Program has been mandated by law to administer the release of specimens and data to research investigators for the following approved purposes:

- Identify risk factors for children’s and women’s diseases
- Develop and evaluate screening tests
- Develop and evaluate screening strategies
- Develop and evaluate treatments.

What are the goals of the California Biobank Program?

- Store DBS under conditions that preserve the samples
- Make DBS more accessible for medical and public health research
- Provide samples for research that will identify risk factors for children’s and women’s diseases.
- Provide samples for research to develop and evaluate screening tests, prevention strategies and treatments.
- Let researchers know the samples are available.

Who manages the Biobank?

The California Biobank Program is part of the California Department of Public Health’s Center for Family Health (CFH). It is administered by the Genetic Disease Screening Program (GDSP) and the California Birth Defects Monitoring Program (CBDMP). The Community Values Panel, comprised of non-Departmental members, advises CBP on a broad range of policies. Program staff and experts from outside of GDSP and CBDMP review studies proposing to use CBP blood specimens and data. This is to ensure that every approved study meets all the criteria defined in State and Federal regulations for research studies and that patient confidentiality is assured. The California Health and Welfare Agency Committee for the Protection of Human Subjects [the State’s Institutional Review Board (IRB)] also reviews each study to ensure it protects people’s rights.

Why use leftover DBS for research?

Dried blood spots contain a wealth of biological information that may be useful for studying birth defects or chronic diseases. Blood may also show if there was exposure to infections or toxic substances before birth. Studying blood may lead to new screening tests. Research may also provide important clues about different factors that impact health or cause diseases not only in California but worldwide.

Is my baby’s entire leftover blood spot sample use for research?

No, only a very small percentage of the total newborn screening dried blood spots have been or are likely in the future to be used for research. Even if your baby’s specimen is selected for research, CBP makes every effort to make sure that not all the leftover spots are used up, so that parental requests can be addressed, including the following.

- Parents may request that their own child’s sample be used to diagnose a disease or determine whether their child was exposed to a virus prenatally.



- Parents may also request that their child's sample be used to assist in investigating crimes like a missing child.
- Parents may request that their child's spot be sent to a specific researcher if they have enrolled their child in a research study.

Are dried blood spots used for cloning or stem cell research?

No. Dried blood spots cannot be used for cloning or stem cell research. Any research requests for specimens that involve cloning or stem cell research will not be approved.

What information about my child will be given to researchers?

In most cases researchers will be given a small punch from a blood spot with no other readily identifiable information. The researcher will not know whose blood spot was used. The researcher might be provided with general information like the fact that the particular blood spot came from a baby whose newborn screening specimen was collected at 24 hours of age, that the baby is a boy and that his mother was 27 years old when he was born. Researchers are never provided with any information that would allow them to determine the identity of the baby whose blood spot they were given.

Has my child's (or my own) dried blood spot been used for research?

For research prior to 2008, it may not be possible for CBP to determine exactly which spots were used in the past, because such information was not maintained. Recently created federal law requires that we be able to tell you if your spots were used in any research studies and if so, what those studies were. New procedures are now in place so the CBP can track use of all samples, but still maintain confidentiality.

How will I or others benefit from the use of my child's blood spots for research?

You or someone in your family, or someone you know may someday be helped by research looking at new ways to diagnose, prevent or treat disease. You will also help ensure that the Biobank represents the entire population of California. No other biobank has as many samples or has such a diverse population as the California Biobank Program. There is great potential that advances in the diagnosis, prevention and treatment of disease may occur because blood spots from the California Biobank Program are used.

Can I decide not to allow my child's blood spots to be used for research?

Yes. You may request that your baby's blood spots not be used for research. For more information and to download the request form, please see our website at: www.cdph.ca.gov/programs/nbs/pages/nbsforms.aspx. Or write to us at Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Richmond, CA 94804.

If you request that the blood spots be destroyed, please realize that the blood spots will not be available to you should you request them at some future time.



Can I change my mind, if I decide at a later date that I do not want my child's blood spots to be used for research purposes?

Yes, you can contact us at any time if you do not want your child's left-over blood spots used for research purposes. At age 18, your child can also ask that his or her blood spots no longer be used for research purposes.

What are the risks if my child's blood spots are used for research?

The only risk is that your child's bloodspot could be identified. The chance this would happen is extremely small because of the steps taken to protect privacy and the fact that the Department of Public Health is bound by law to protect your and your child's personal private information. In the more than 30 year history of our program, for the approximately 16 million blood spots we have stored and the thousands of blood spots we have shared with researchers, there has NEVER been a recorded instance of a breach of privacy.

How is privacy protected?

CBP staff work in a secured facility and must, as a condition of their employment with CDPH, sign an agreement to keep all information that could identify a mother, a child or a family private. In addition to California state laws, the Genetic Information Nondiscrimination Act (GINA) provides protection at the federal level.

The CBP and the Institutional Review Boards (IRB) that approve all research requests are committed by law to minimize the risks of releasing private information. The CBP provides only the minimum amount of data needed to conduct the research. Every possible step is taken to provide only non-identifiable data to researchers whenever possible.

Researchers who receive data and specimens from CBP are legally required to protect the privacy of the associated persons. This is accomplished by requiring that researchers sign a biospecimen/data use agreement that precludes them from using or sharing the specimens, or products thereof, and information that comes from the specimens for any purpose except the approved research project. They are not allowed to use such information to attempt to identify the person from whom the specimens were taken.

Do law enforcement officials or insurance companies have access to the specimens in the Biobank?

No. Under state law the leftover blood spots and identifiable information it contains are subject to strict confidentiality protections and are not subject to forced disclosure to third parties. Specifically, "...no part of this confidential information shall be available for subpoena, nor shall it be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding..."ⁱ



How can I find out more about the California Biobank Program?

If you have any questions about the CBP or about blood spots being used for research, please contact:

The California Biobank Coordinator

Phone: 510-412-1500

Email address: BiobankProgram@cdph.ca.gov

ⁱ Health and Safety Code, Division 102, Vital Records and Health Statistics, Part 2 Population and Public Health Surveillance, Chapter 1 Birth Defects Monitoring, 103850(g)