

Frequently Asked Questions
California Department of Public Health, Center for Family Health
Prenatal Screening, Blood Specimens, and the California Biobank Program

What is the Prenatal Screening Program (PNS)?

The Prenatal Screening Program is a statewide public health program for pregnant women that can help detect some birth defects such as Down syndrome, Trisomy 18, Trisomy 13, neural tube defects and abdominal wall defects. Prenatal care providers are required to offer this screening to any woman who enters their care by 20 weeks of pregnancy. Women may choose or decline to participate in prenatal screening. When a woman's prenatal care provider offers her the screening, the pregnant woman signs a form either consenting to or declining the screening. The consent form indicates that after screening the leftover blood specimen may be used for research purposes unless the patient opts out. If the patient has not opted out, her blood specimen may be stored by the California Biobank Program (CBP) and may be used for research. For more information about the Prenatal Screening Program please see our website at: www.cdph.ca.gov/programs/nbs/pages/nbsforms.aspx.

How is Prenatal Screening done?

A small amount of blood is taken from a pregnant woman's arm during the 1st and/or 2nd trimester of pregnancy and is sent, along with a test request form, to the assigned State screening laboratory. Prior to sending it to the testing lab, the draw station (the place that drew the blood) will spin the blood to separate the liquid portion (serum) from the red and white blood cells portion of the blood. At the screening laboratory, some of the serum will be used in the testing process. The test results, health information about the woman and a nuchal translucency ultrasound measurement (when available) are all combined to estimate the chance (risk) that the woman's fetus has a particular birth defect.

What happens to the PNS specimen after screening is done?

If the woman allows the leftover specimen to be used for research, the specimen may be saved and sent to the California Biobank Program for processing and freezer storage. Only some of these specimens are sent to the Biobank. Prior to freezing, the leftover serum is poured off into two freezer-safe tubes with the cells portion remaining in the original tube. All three tubes are labeled with a unique bar code number. There are no identifying names on any of the tubes. The three tubes are then placed in separate freezers.

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.

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How is the California Biobank Program Structured?

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. Studies proposing to use CBP blood specimens and data are reviewed by Program staff and experts from outside of GDSP and CBDMP. 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.

What does the California Biobank Program Store?

Between 2000 and 2014, the CBP has stored in freezers approximately 1 million prenatal screening specimens. In addition, the CBP has stored in freezers over 16 million newborn dried blood spot specimens beginning in 1982 (see Newborn Screening FAQ for more information). Screening program data linked to specimens and to vital records data (live births, fetal deaths and deaths) are also stored by the CBP. Altogether, the CBP is one of the largest biobanks of its kind in the world.

Why use leftover blood for research?

Blood contains 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 (such as pesticides, lead, etc.) 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.

What kind of research is allowed by the California Biobank Program?

Only research that fits into one or more of the approved purposes described above are allowed by the CBP. The Prenatal Screening Program does not use prenatal blood specimens for cloning or stem cell research and will not approve any research request for specimens that involve cloning or stem cell research. A list of published articles using CBP specimens or data can be found at [Department Publications](#).

What are examples of research that have used prenatal blood specimens?

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Studies involving prenatal blood specimens include the study of:

- heart defects in newborns
- the impact of the exposure of toxins in the environment to diseases in children
- environmental tobacco smoke and pregnancy outcome

Is there a record if a PNS blood specimen was stored or used for research?

Yes. The CBP can determine whether a particular woman's prenatal blood specimen was stored or used for research and the specific research project for which it was used. The program began storing prenatal blood specimens in 2000.

May a woman change her mind about a leftover PNS blood specimen being used for research?

Yes. Even if a patient previously allowed her leftover PNS blood specimen to be used for research, she may request that her blood specimen be destroyed and no longer be used for research. To make a request, please write to:

California Biobank Coordinator
850 Marina Bay Parkway, F175, MS 8200
Richmond, CA 94804.

Please include the patient's name and contact information including a phone number and email address. It will not be possible to retract any previous research use of the specimen should that have occurred prior to notification.

How is privacy protected?

CBP staff work in a secured facility and must sign as a condition of their employment with CDPH 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. Some projects may include release of identifying information after project-specific patient consent.

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

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researchers sign a biospecimen/data use agreement that precludes them from using or sharing the specimens and information that comes from the specimens, such as DNA, 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 insurance companies have access to the California Biobank Program?

No. Under state law, the California Biobank Program and the prenatal blood specimens and the identifiable information they contain 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 further questions about the California Biobank Program or about prenatal blood specimens being used for research, please contact the California Biobank Program Coordinator at:

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)