



Frequently Asked Questions

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Introduction

Sutter Health has made a strategic commitment to Precision Medicine – a medical care model that seeks to integrate an individual’s genetic, metabolic, and environmental information to improve and personalize disease prediction, prevention, and treatment. An essential part of this commitment is the expansion of our capabilities in support of Precision Medicine research focused on the role of genomics, metabolic, and proteomics on health and treatment. The key to a Precision Medicine research capability is the availability of biological samples for use in

research. As the cornerstone to this endeavor, Sutter Health is implementing a system-wide serum and DNA biobank.

The Sutter Health Biobank will involve obtaining serial serum and DNA samples and self-reported questionnaire data from approximately 100,000 patients from across the system. Serial samples can be used to evaluate changes in DNA (i.e., base pairs, methylation, etc.), DNA expression, and other biological mediators of health or disease. These biological samples, linked to patient-reported and health history data, will be used to support future research investigations in precision medicine.

Answers to Frequently Asked Questions

1. What is a biobank?

A biobank is a collection of biological material with corresponding health information that can be used for research purposes. The Sutter Health Biobank stores human blood from a large number of Sutter Health patients for medical research. This blood is stored in freezers at –80°C as frozen samples of whole blood and blood components called plasma and serum.

2. What is the purpose of the Sutter Health Biobank?

Blood contains genetic and other important information about our health. The purpose of the Biobank is to collect and store blood samples from patients so that it can be combined with health information from their medical records. This will help researchers perform studies in the future to better understand what allows people to live longer and stay healthy as they age. For

example, genes and other factors, such as smoking or body mass index, can influence how healthy a person is as they age.

3. What is involved if I agree to participate?

We will ask you to complete a short questionnaire online. It asks about your general health, your lifestyle, and activity level. You can select a “prefer not to answer” response to any of the questions. The questionnaire takes about 5 minutes to complete online.

We will get some health information from your medical record. Examples of these include test results, medical procedures, images (such as X-rays), and medicines you take. We are also asking your permission to collect mental health information from your medical record. We will use your medical record from time to time to update this information.

We will collect a blood sample from you at an upcoming Sutter Health laboratory visit, at the same time you are having blood collected as part of your routine clinical care. There is no need to come in separately for the Biobank blood collection.

4. How will the Biobank store my blood samples and information?

The Biobank assigns a code to your information and blood samples. Your name, medical record number, date of birth, or other information that easily identifies you will not be stored with your samples or health information. Researchers who want to perform future research must apply for permission to access samples and health information, and we will not share information that directly identifies you with them. Your blood sample will be securely stored in freezers maintained by an external party with whom we work. Your health information will be stored in a Sutter Health research database.

5. Who will use my samples and information?

Blood samples and health information may be used by Sutter Health researchers, or by medical research organizations such as universities and drug companies or technology companies that develop health-related products. Researchers and medical research organizations who want to perform future research must apply for permission to access blood samples and health information.

6. How do I benefit from participating in the Biobank?

Although you will not get a direct benefit from taking part, you may want to participate to help researchers make discoveries that might help people in the future. It can take many years to confirm and develop scientific methods, technologies and tests. Samples need to be analyzed from a large number of people before any conclusions can be made. You will not receive any

financial benefits for taking part in the Biobank, but there are no costs to you or to your insurance.

7. How long will the Biobank keep my sample and information?

We will store your blood sample and information indefinitely. However, you can revoke your permission at any time.

8. What if I change my mind about the use of my sample and information?

You can withdraw your permission for the Biobank to use your blood sample or information at any time. If you do, we will ask that you let us know in writing what you would like us to do with your blood and medical information. It will not be possible to withdraw any samples or information that have already been given to researchers. Also, we may need to keep some information to maintain the integrity of the study. If you decide to withdraw from the Biobank, it will not affect your medical care or eligibility for benefits.

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9. Will I receive results of the research done using my sample?

You will not get individual results from the research done using your sample, and your provider will not receive your results. Results will not be added to your electronic health record, but we will place a copy of your signed consent document there. You will not be informed of the specific research studies that use your blood sample and health information. However, you can get general news about the kinds of studies being done at the Biobank website.

Visit <http://sutterhealth.org/research/biobank> to learn more.

10. What types of research will be done with my sample?

Many types of research may be done with your sample and health information. Some studies do genetic research to look at your DNA and genes. DNA and genes are the components of your blood that contain genetic information. Other types of research may look at proteins and other components of your blood.

Your sample may also be used as a healthy control in research to determine the differences in why some people develop health conditions while others do not.

Many other types of research may be possible in the future, and we cannot predict all of the research questions that will be important. As researchers learn more and make new

discoveries, your blood samples and information may be used to answer new questions that have not been thought of yet.

11. Can I choose what my sample is used for?

No, participants cannot choose how researchers will use their blood sample and health information. These types of choices could interfere with the outcome of the research or complicate the research plan too much.

12. What are the risks of participating in the Biobank?

The main risk of participating in the Biobank is a possible loss of privacy. We believe the chance this will happen is small because we protect your privacy by using a unique code to label your blood sample and health information.

There is a risk that someone could get access to the data we have stored about you. In some cases, information about taking part in genetic research may influence insurance companies or employers regarding your health. There are laws against the misuse of genetic information, but they may not give full protection.

These laws include the Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects individuals from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

There is a risk that drawing blood from your arm may cause brief pain and/or bruising.

13. How is my privacy protected?

Your privacy is very important to us and we will make every effort to protect it. We will remove your name and other identifiers from your sample and information, and replace them with a code number. We will not give information that identifies you to anyone except a limited number of Biobank staff, or if required by law. Researchers who use your blood samples and health information will not be able to directly identify you and they will not be able to contact you.

14. How long will it take to participate in the Biobank?

You should expect to spend a total of no more than thirty (30) minutes to review and sign the online consent form. Then you will be prompted to answer an online questionnaire, which takes about five (5) minutes to complete.

When you have an upcoming Sutter Health laboratory visit, we will collect the Biobank blood sample at that same time. This will add approximately three to five minutes to your lab visit. There is no need to come in separately for the Biobank blood collection.

15. What type of oversight does the Biobank have?

The Biobank is approved by the Sutter Health Institutional Review Board, which reviews research projects to protect the safety, rights, and welfare of human subjects involved in research.

The design and operation of the Biobank is conducted under the oversight of the Precision Medicine and Biobank steering committee. The committee consists of scientific researchers, physicians, and administrators to develop the goals of the Biobank and implement them.

The Biobank governance committee reviews research proposals to use the Biobank blood samples and health information to ensure research is done ethically, has scientific value, and is feasible. The committee consists of scientific researchers, privacy and compliance experts, as well as members from the community.

16. How was I selected to receive an invitation?

We are inviting patients who have a Primary Care Provider at Sutter Health, and we received information from Sutter that you are a current patient.

17. How many people will be enrolled?

Approximately 100,000 patients will be enrolled over the next three years.