

HUMAN RESEARCH CONSENT FORM
Sutter Health Research Biobank Consent & Authorization Form

SUTTER HEALTH
09July2020
IRB APPROVED

The information below and on the following pages will help you decide if you want to take part. Please take all the time you need to read this. You may contact the Biobank team toll free at **1-855-771-7499** if you have additional questions.

Because you have been seen by a Sutter doctor, we are asking for you to let us collect and store a small amount of your blood in the Sutter Health Research Biobank, referred to as the “Biobank” throughout this form. If you choose to join, we will collect a blood sample the next time you are having your blood drawn for any other reason. No need for an extra trip to the lab or an extra needle stick.

Blood contains genetic and other important information about our health. Researchers will combine information from blood samples with information from medical records to better understand a number of specific diseases and what allows people to live longer and stay healthy as they age.

In addition, if you are undergoing a diagnostic or therapeutic procedure and your physician determines that there is surplus tissue – tissue not needed any longer for diagnostic or therapeutic purposes - you may choose to allow us to collect the surplus tissue that would otherwise be discarded. Examples of surplus tissues are biopsy tissue, cerebrospinal fluid, joint fluid, or surgically-removed tissue. Contributing surplus tissue is optional for this study—you can decide you only want to provide blood samples and still be in the study. You will be asked to indicate whether you want to contribute surplus tissue at the end of this consent form. You may also decide to change your permissions about tissue donation at a later date.

As you read, keep in mind:

Taking part is voluntary and entirely your choice. You can choose to take part or not to take part.

If you choose to take part but later change your mind, you can quit at any time. Just call toll free 1-855-771-7499 and let us know. We will send you a form so you can tell us in writing what you would like us to do with any of your blood that we have not already given out for study.

No matter what you decide, now or in the future, it will not affect your medical care or eligibility for benefits.

What is the purpose of this research project?

The purpose of the Biobank is to collect and store blood and tissue samples from patients so that they can be combined with health information from patients’ medical records. This will help researchers answer questions in future studies about health, healthy aging, and specific diseases. The diseases of specific interest include multiple sclerosis and other demyelination diseases; Parkinson’s disease, amyotrophic lateral sclerosis (ALS) and other movement disorders; certain cancers; heart conditions; migraine headaches;

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Alzheimer's disease and other neurodegenerative conditions; rheumatoid arthritis and other autoimmune diseases; rare diseases; healthy aging; and other health conditions.

What are we asking of you?

If you agree to take part:

We will ask you to sign this form. Once you sign, we will send you an email containing a link to your signed copy, so that you can save or print it.

We will ask you to complete a short questionnaire online. It asks about your general health and lifestyle and takes about 5 to 10 minutes to complete. The questionnaire will be securely stored for use in research.

After you sign the consent form and complete the questionnaire:

We will get some health information from your medical record. Examples include test results (including genetic 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 small sample of your blood during future visits to a Sutter lab. The small sample (about 4 tablespoons of blood, up to 6 tubes) will be collected at the same time you have blood drawn for any other reason. This avoids a separate needle stick for research. We will collect blood from you up to three times. Blood draws will be approximately once per year.

If you elect to participate in tissue donation, we will save excess tissue—tissue that is extra and is no longer needed for your diagnosis or treatment—after your procedure (lumbar puncture, biopsy, surgery, etc.). If you select this option below, we may store leftover tissue samples that would otherwise be discarded/thrown away after they are no longer needed by your treatment team. These samples can then be used to learn more about medical conditions.

We will store your sample in the Biobank. Your permission to keep and use your sample and medical information does not expire unless you revoke that permission. Your blood sample will be labeled with a unique code (no name). Blood samples will be securely stored in freezers maintained by an external party with whom we work.

It is important for you to understand how we will use and store your genetic information before you agree to take part in this study.

We may store some of your genetic and health information in research databases. Researchers must apply for permission to use the databases. Information that directly identifies you will not be shared with researchers.

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We will let researchers use the blood/tissue and health information for approved studies. Researchers from Sutter Health, universities that work with Sutter, and drug- or technology companies that develop health-related products can apply to use the blood samples and information. We will not give researchers your name or any other information that could directly identify you.

How will information about you be kept private?

Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

We will remove your name and other identifiers from your blood sample and health information, and replace them with a code number. The Biobank will keep the list that links the code number to your name separate from your sample and information. Only a few members of the Biobank staff will have access to the list. Biobank staff must sign an agreement to keep your identity a secret.

We will not give information that identifies you to anyone except a limited number of Biobank staff, or if required by law.

Some recipients of your sample and information may not be required to comply with the Privacy Rule. There is a potential that the information may be disclosed by the recipient.

We have obtained a Certificate of Confidentiality from the Federal Government.

This Certificate protects your privacy by allowing us to refuse to release your name or other identifying information to anyone outside of the research project and institution, even by a court subpoena, except as described below. In the unlikely event of a federal audit, we may have to reveal your name, but only to authorized representatives.

The Certificate of Confidentiality does not prevent release of your information when:

You or a member of your family voluntarily release information about yourself or your involvement in this research.

You give written consent to an insurer, employer, or other person to receive research information.

We are required to release your name and other identifying information to the appropriate officials when:

We find or suspect child abuse, elder abuse, or intent to harm yourself or others.

You have a reportable communicable disease that State or Federal Law requires us to report, such as tuberculosis, HIV infection or syphilis.

What are the possible risks?

There is a risk that drawing blood from your arm will cause brief pain and/or bruising. These are common risks related to drawing blood.

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There is a risk that someone could improperly get access to the data we have stored about you. In some cases, it could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small. In rare instances, personal information has inadvertently been shared with outside companies that help Sutter Health run studies. These companies have signed agreements to protect your information if this happens, and in these cases the information has been destroyed. However, absolute confidentiality cannot be guaranteed.

There is a risk that someone could trace the information in a scientific database back to you. Even without your name or other identifiers, your genetic information is unique to you. The chance that someone could identify you may grow in the future with the development of new ways to trace information back to individuals.

What other information should you know?

Possible benefits

You will not get direct benefit from taking part.

The main reason you may want to take part is to help researchers make discoveries that might help people in the future.

You will not be paid for taking part.

If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

Costs

There are no costs to you or your insurance.

Results

Your sample will be used for research only.

You will not get individual results from research done using your sample.

Your provider will not receive your results from research done using your sample.

You can get general news about the kinds of studies being done through the Biobank at the Sutter Health Website.

Remember that taking part is your choice and you can change your mind at any time.

You can choose to take part or not to take part. If you choose to take part but later change your mind, you can quit at any time. Just call **855-771-7499** and let us know. We will send you a form so you can tell us in writing what you would like us to do with any of your blood or medical information that we have not already given out for study, or that we need to keep to maintain the integrity of the study.

No matter what you decide, now or in the future, it will not affect your medical care or eligibility for benefits.

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For questions about this project call the Biobank at 855-771-7499.

For questions about your rights as a research participant call the Sutter Health Institutional Review Board at 855-771-7498.

1. I understand the purpose of the Sutter Health Biobank, the procedures involved, and the risks and benefits. I do not have any additional questions now, and I know who to contact if I have more questions. Select **Yes** to take part in the Biobank. Select **No** if you do not want to take part in the Biobank.

☐ Yes ☐ No Initials

2. I agree to the storage and use of my blood, including genetic information, by the Sutter Health Research Biobank, and for future research. Select **Yes** to take part in the Biobank. Select **No** if you do not want to take part in the Biobank.

☐ Yes ☐ No Initials

I can still take part in the Sutter Health Biobank even if I answer No to the following questions.

3. I agree to the storage and use of my surplus tissue from medical procedures to the Sutter Health Biobank.

☐ Yes ☐ No Initials

4. Someone from the Biobank can contact me once a year to update my personal information.

☐ Yes ☐ No Initials

5. I specifically authorize release of mental health information from my medical record.

☐ Yes ☐ No Initials

Signature of Participant

Date

Printed Name of Participant