

Protocol Title: **Partners HealthCare Biobank**
Principal Investigator: Scott T. Weiss, MD, MS

Description of Subject Population: Individuals seen at Partners HealthCare

1. What is the purpose of this research?

Researchers at Partners HealthCare System (Brigham & Women’s Hospital, Massachusetts General Hospital, and other Partners institutions) are studying how genes and other factors affect people’s health and contribute to human disease. To perform this research, we are asking patients at Partners to participate in the Partners HealthCare Biobank (Partners Biobank or Biobank) with blood samples to be stored in a research tissue bank (the “Biobank”). Taking part in this research study is up to you. Your decision to participate will not affect your clinical care in any way. Your participation can help us better understand, treat, and even prevent diseases that affect your loved ones, your family’s future generations, as well as the larger community.

If you have any questions before you sign this consent form or after you join the study, you can contact the Partners Biobank staff at 617-525-6700 from Monday - Friday 9a – 5p. The person in charge of the Partners Biobank is Scott T. Weiss, MD. If you want to speak with someone **not** directly involved in the study, contact the Partners Human Research Committee at 857-282-1900. There is also an attached fact sheet that expands on the consent form to provide definitions and additional information.

2. What will happen in this study?

- You may be asked to donate a blood sample of up to 5 tubes (about 3 tablespoons). If blood samples for the Biobank are not collected today, they may be collected at a future time when you have a blood draw ordered by your doctor. We may also use blood, urine or tissue samples collected as part of your clinical care now or in the future that would otherwise be thrown away.
- We will also look at your medical records now and in the future to update your health information. We will store some of your health information in the study database.
- We may ask you to complete questionnaires about your health.
- We may contact you in the future to get additional information and ask if you are interested in joining other research studies.
- A notation that you are taking part in this research study may be made in your electronic medical record.

3. For what type of research will my samples be used?

- We plan to do many types of biological and genetic research with your sample, for example, research on heart disease, cancer, diabetes, mental illness, or reproduction to name a few. Genetic

Subject Identification

research may include looking at some or all of your genes and DNA to see if there are links to different types of health conditions.

- We may create a “cell line” from your sample that will allow researchers to have an unlimited supply of your cells for research.
- We may use your cells to create pluripotent stem cells. This type of cell can be used to create different types of tissue, for example, heart, muscle, or lung cells. Your cells might be used in research that alters genes in the cells in order to study different diseases and normal healthy processes. Your cells might be mixed with other human cells, animal cells, or grown in lab animals like mice.
- We may share your samples and any cell lines that are created, your DNA sequence information, your health information, and results from research with other central tissue or data banks, such as those sponsored by the National Institutes of Health, so that researchers from around the world can use them to study many conditions.

4. Will I get results of research done using my samples?

- You may receive a newsletter or other information that will tell you about the research discoveries from the Biobank. This newsletter will not identify you or describe any of your personal results. It may be sent via Patient Gateway email if you’re on Patient Gateway, by unencrypted email to your email address if you gave us one, or by US mail to your home address.
- Generally, we will not return individual results from research using your samples and data to you or your doctor. Research using your sample is just a stepping stone in learning about health and disease. Most of the findings that come from studying your sample will not be relevant to your personal health. However, in the future, this may change.
- It is important to remember that research results are not always meaningful and are not the same as clinical tests. While you should not expect to receive any results from your participation in this research, if experts from the Biobank decide that research results from your sample are of high medical importance, we will attempt to contact you. In some situations, follow up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these tests and any follow up care, including deductibles and co-payments.
- It is possible that you will never be contacted with individual research findings. This does not mean that you don’t have or won’t develop an important health problem.
- In the future, when research results are published, they may show that certain groups (for example, racial, ethnic, or men/women) have genes that are associated with increased risk of a disease. If this happens, you or others may learn that you are at increased risk of developing a disease or condition.

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5. What are the benefits to me? Will I be paid for my samples?

- You will not directly benefit from research conducted on your samples stored in the Biobank. We hope that research using the samples and information will help us understand, prevent, treat, or cure diseases.
- You will not receive payment for your samples. In some locations, your parking cost may be covered or you may receive a cafeteria voucher.

6. What are the costs to me to take part in the research tissue bank?

There are no costs to you to participate in the Biobank.

7. How are my samples and health information stored in the Biobank?

Staff at the Biobank will assign a code number to your samples and health information. Your name, medical record number, or other information that easily identifies you will not be stored with your samples or health information. The key to the code will be stored securely in a separate file.

8. Which researchers can use my samples and what information about me can they have?

- Your coded samples and health information may be shared with researchers at Partners institutions. They may also be shared with researchers at non-Partners institutions or with for-profit companies that are working with Partners researchers. Your samples will not be sold for profit. We may use your samples and information to develop a new product or medical test to be sold. The hospital and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.
- We will only share information that identifies you with researchers within Partners who have approval of the Partners ethics board. We will not share information that identifies you with researchers outside Partners.
- In order to allow researchers to share research results, agencies such as the National Institutes of Health (NIH) have developed secure banks that collect and store research samples and/or data from genetic studies. These central banks may store samples and results from research done using Partners Biobank samples and health information. The central banks may share these samples or information with other qualified and approved researchers to do more studies. Results or samples given to the central banks will not contain information that directly identifies you. There are many safeguards in place at these banks to protect your privacy.

9. How long will the Biobank keep my samples and information?

We will store your samples and information indefinitely.

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10. Can I stop allowing my samples and information to be stored and used for research?

Yes. You can withdraw your permission at any time. If you do, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. If you decide to withdraw please contact the Partners Biobank staff in writing. In case we need to contact you about medically important research results from your sample, please notify the Partners Biobank staff if your address changes.

Partners Biobank 65 Landsdowne St, Room 142 Cambridge, MA 02139	Phone: 617-525-6700 FAX: 617-768-8513 Email: biobank@partners.org
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11. What are the risks to me?

- The main risk of allowing us to use your samples and health information for research is a potential loss of privacy. We protect your privacy by coding your samples and health information.
- There is a risk that information about taking part in genetic research may influence insurance companies and/or employers regarding your health.
- Research results obtained in this study will not be placed in your medical record unless we contact you with a finding of high medical importance.
- We do not think that there will be further risks to your privacy by sharing your samples and/or whole genome information with other researchers; however we cannot predict how genetic information could be used in the future.
- There is a very small risk of bruising or infection from drawing blood similar to what might occur from a routine blood draw that you get for your doctor.

12. If I take part in the Biobank, how will you protect my privacy?

In general, health information that identifies you is private under federal law. However, you should know that in addition to Partners researchers the following people or groups may be able to see, use, and share your identifiable health information from the research and why they may need to do so:

- Any sponsor(s) of this Biobank and the people or groups it hires to help with the Biobank
- The Partners ethics board that oversees the project and the Partners research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or organizations that we hire to do work for us, such as data storage companies, insurers, and lawyers

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- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- We share your identifiable health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

13. Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

Informed Consent and Authorization for Collection of Samples and Health Information for Research

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research study to the subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date

Time

Subject Identification

Signature of Subject: I give my consent to take part in this research study and agree to allow my samples and health information to be used and shared as described above.

Subject

Date

Time

Email