

Research Consent Form

Protocol Title: **Mass General Brigham Biobank**
Principal Investigator: Elizabeth W. Karlson, MD, MS

Description of Participant Population: Individuals seen at **Mass General Brigham**

1. What is the purpose of this research?

Researchers at Mass General Brigham (MGB) are studying how genes, biomarkers, and other factors affect people's health and contribute to disease. To perform this research, we are asking our patients to participate in the Mass General Brigham Biobank (MGB Biobank or Biobank) by providing samples for research purposes, including for genetics. Your participation can help us better understand, treat, and even prevent diseases that might in the future affect you, your family, and your community.

Taking part in this research study is up to you. If you decide not to participate you can still get medical care at MGB now or in the future. If you have any questions about the MGB Biobank, you can contact Biobank staff at 617-525-6700 or biobank@mgb.org. The person in charge of the Biobank is Elizabeth W. Karlson, MD, MS. If you want to speak with someone **not** directly involved in the study, contact the MGB Institutional Review Board (IRB) at 857-282-1900. You can talk to them about:

- A complaint, problem or concern
- Ask questions, offer input, or obtain information
- Your rights as a research participant

2. What will happen in this study?

- You may be asked to donate a blood sample of up to 5 tubes (about 3 tablespoons).
- We may also use blood, other bodily fluids, stool, or tissue samples collected as part of your clinical care now or in the future that would otherwise be thrown away.
- In the future, we may also collect additional blood samples when you have blood drawn for your clinical care (about 2 tablespoons per draw).
- We will look at your electronic health records to inform researchers. Some of your health information will be stored in the study database.
- We will ask you to complete a questionnaire about your health when you join the study and we may ask you to complete optional questionnaires in the future.
- We may contact you in the future to get additional information and ask if you are interested in joining other research studies.

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, we may conduct research on heart disease, cancer, diabetes, and/or many other diseases. We may do genetic research on the DNA in your sample. DNA is the material that makes up your genes. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work. Genes are passed from parent to child.

A whole genome analysis on your DNA sample may be done. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to many diseases or conditions.

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

Generally, we will not give you or your doctor information about the individual results of research analyses done with your data and/or samples. While you should not expect to get these research results, if experts from the study decide that research results from your data and/or samples are of high medical importance, we will attempt to contact you. It will be your choice whether to receive the results or not. In case you decide to receive the results, follow-up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these follow-up tests and any follow-up care, including deductibles and co-payments.

It is possible that you will never be contacted with individual research results. This does not mean that you don't have or won't develop an important health problem.

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 individual results.

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

It is possible you will not directly benefit from research conducted on your data and/or samples stored in the Biobank. However, if researchers find results that are important to your health, you may directly benefit. Results about genetic or other biomarkers may help your healthcare provider take better care of you. They may be able to prevent or find a health condition early. This could help you get better treatment or more appropriate medication.

We will not pay you to allow us to store your data and/or samples and to allow research to be done with your data and/or samples.

We may use your data and/or samples to develop a new product or medical test to be sold. The sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your data and/or samples are used for this purpose.

6. What are the costs to me to take part in the MGB Biobank?

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

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

Biobank staff will assign your data and/or samples a code number and store them securely using MGB storage tools. They will not keep your name or other information that could identify you with your data and/or samples. They will use the code number to connect your samples to your health information that is stored in a computer database. The computer database is protected with a password. Only Biobank staff will know the password.

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

Your data and/or samples may be shared with researchers at MGB, at other academic institutions, or at for-profit companies that are conducting research. Your data and/or samples will not be sold for profit.

Researchers at MGB will be allowed to work with your identified data and samples if they have approval from the MGB ethics board. Researchers outside of MGB will not be given the key to the

code that links your data and/or samples to your name or other direct identifiers. You will not be asked to provide additional informed consent for these uses.

In order to allow researchers to share data and/or samples, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These repositories may also analyze and store DNA samples as well. These central repositories will store your genetic information and samples and give them to other approved and qualified researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

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

We will store your samples and information indefinitely.

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 no longer be shared with researchers. However, it will not be possible to take back samples and information that have already been given to researchers. If you decide to withdraw please contact Biobank staff by email at biobank@mgb.org, by phone at 617-525-6700, or by mail at Mass General Brigham Biobank, 65 Landsdowne St. Cambridge, MA 02139.

11. What are the risks to me?

The main risk of allowing us to use your samples and information for research is a potential loss of privacy. We protect your privacy by labeling your samples and information with a code, and keeping the key to the code in a password protected database. Information that could be used to directly identify you will only be shared with researchers within MGB who have approval of the MGB ethics board. Information that likely could be used to identify you will not be shared with researchers outside MGB.

There is a risk that genetic information obtained in a research study may influence insurance companies and/or employers regarding your health. If you decide to have research results confirmed by a certified clinical lab, the clinical results will be placed in your medical record.

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?

Federal law requires MGB to protect the privacy of health information and related information that identifies you. We refer to this information simply as “identifiable information.”

In this study, we may collect health information about you from:

- Past, present, and future medical records

- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- MGB research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within MGB who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The MGB ethics board that oversees the research and the MGB research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- 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)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. Entities other than the MGB Biobank will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside MGB, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Your Privacy Rights

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

13. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay, including as described in this form. For example, you may give them permission, as you are doing in this form, to release information to insurers, medical providers or other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate.

Even with these measures to protect your privacy, once your identifiable information is shared outside MGB, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information will not be used for these purposes without your specific permission.

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