

Subject Name:

Date of Birth:

Subject

Protocol Title: A community-based personalized omics profiling to assess biomarkers of aging

Principal Investigator: Vadim N. Gladyshev

Site Principal Investigator: Vadim N. Gladyshev

Description of Subject Population: Healthy volunteers 18 years or older

## **Collection of Samples and Health Information for Research**

### **About this consent form**

Please read this form carefully. It tells you important information about the collection and storage of tissue samples and data for research. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to give your permission. We will give you a signed copy of this form to keep.

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## Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a generally healthy volunteer 18 years or older, at least 110 lbs, free of cold and flu symptoms the day of collection, had no infections within two weeks prior to collection, no symptoms of a heart condition within the six months prior to collection, and no known sickle cell disease or anemia, have not donated more than 550 ml during preceding eight weeks and no more than one blood draw has occurred during the preceding week.

We are doing the research to assess the population's molecular variation and dynamics. If you agree, you will donate 50 ml (about 10 teaspoons) of blood and a few noninvasive and simple functional tests to assess your physical and cognitive performance.

during your visit. You will be in the study for 12 months if you decide to stay for the whole study.

The main risks of being in the study are risks from taking blood from your arm that is minimal, which may involve a little pain, a bruise or local infection at the site.

You will receive a \$50 gift certificate, as well as complimentary virtual access to stream the Biomarkers of Aging Conference for this year, upon completion of your participation. You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Mahdi Moqri, PhD is the person in charge of this research study. You can call him at 6175255141 M-F 9-5 or email him at [mmoqri@bwh.harvard.edu](mailto:mmoqri@bwh.harvard.edu)

If you have questions about the scheduling of appointments or study visits, call Mahdi Moqri at 6175255141 or email him at [mmoqri@bwh.harvard.edu](mailto:mmoqri@bwh.harvard.edu)

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject

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- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

## Detailed Information

### What will happen if you take part in this research tissue bank?

We are asking you to allow us to collect and store your blood in a research tissue bank. In addition, we are asking you to complete a questionnaire regarding your general health, any medication, physical activity, food intake, and stress levels. We will also conduct four noninvasive and simple functional tests to assess your physical and cognitive performance. The tests include a simple standing balance test, measuring 6 meter walking speed, grip strength using a digital grip test, and a simple digital cognition test.

If you agree, your blood samples will be frozen and sent to the bank. We are also asking for your permission to store some of your health information and collected data with your samples so that your samples will be more useful for research. We plan to continue to review your medical record to update your health information in the tissue bank computer database.

We would also like your permission for the tissue bank staff to contact you in the future. This could be at a medical visit or by phone to get updated information about your medical condition or health status.

### How are your samples stored?

Staff at the bank will assign your sample a code number and store it in a freezer. They will not keep your name or other information that could identify you with your sample. They will use the code number to connect your sample to your health information that is stored in a computer database. The computer database is protected with a password. Only staff at the bank will know the password.

### Which researchers can use your samples and what information about you can they have?

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Your samples will be made available to researchers at Mass General Brigham institutions, as well as non-Mass General Brigham academic institutions. Occasionally, your samples may be shared with for-profit companies that are working with Mass General Brigham researchers on a specific research project. Your samples will not be sold to anyone for profit. The tissue bank will usually provide samples with limited information that does not directly identify you.

- As described above, all of the samples stored in the bank are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the tissue bank staff, and will be securely stored.
- Researchers at Mass General Brigham institutions, whose studies have been approved by the hospital ethics board, may be allowed to review your medical record to collect more health information about you. The ethics board is a group that independently reviews and watches over all research studies involving people. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected.
- Researchers outside of Mass General Brigham will not be given the key to the code that links your sample and medical information to your name or other direct identifiers.

## **For what type of research will your samples be used?**

Your samples and information will be used mainly to better understand blood integrative omics at the personal and population level on its variation and dynamics for health monitoring and preventative medicine.

The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat aging-related diseases. It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important over the next few years. As we learn more, there are new research questions and new types of research related to aging-related diseases may be done.

Your samples and information may also be used for research on other conditions; for example, as comparisons to other diseases. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer, and others.

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We plan to do genetic research on the DNA in your tissue sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to "many diseases or conditions".

In order to allow researchers to share test results, 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 banks may also analyze and store DNA samples, as well. These central banks 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.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.

### **How long will your samples and information be kept?**

There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are "used up."

The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

### **Can you stop allowing your samples and information to be stored and used for research?**

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Subject

Yes. You have a right to 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 your permission, you should contact the tissue bank's staff, Dr. Mahdi Moqri in writing via email at [mmoqri@bwh.harvard.edu](mailto:mmoqri@bwh.harvard.edu).

### **Will you get results of research done using your samples?**

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

### **What are the risks?**

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password protected database.

Information that could be used to identify you will only be shared with researchers within Mass General Brigham who have approval of the Mass General Brigham ethics board. Information that likely could be used to identify you will not be shared with researchers outside Mass General Brigham.

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

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Your doctor will explain the risks of the routine medical procedure - a blood draw - you are having. In some cases, your doctor will ask you to sign a separate clinical consent form that explains the risks of the procedure. Allowing your samples to be placed in the bank will not change the risks of the medical procedure itself.

The main risks of being in the study are risks from taking blood from your arm that is minimal, which may involve a little pain, a bruise or local infection at the site. There is a minimal risk of falling during the walking or balance tests, and a member of the study staff will assist you, as needed.

### **What are the costs to you to take part in the research tissue bank?**

There is no cost to you to have your samples in the bank or for the research using your samples.

### **Will you be paid for your samples?**

You will receive a \$50 gift card for your participation in our study, as well as complimentary virtual access to stream the 2024 Biomarkers of Aging Conference.

We may use your samples and information 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 samples or information are used for this purpose.

### **Can you still get medical care within Mass General Brigham if you don't take part in this research tissue bank or if you stop taking part?**

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now, or have a right to receive.

Taking part in the bank is up to you. You can decide not to allow your samples and information to be placed in the bank. If you decide to take part now, you can change your mind and drop out later.

Subject Name:

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Subject

## **What happens if you are injured as a result of taking part in this research study?**

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

## **If you take part in this research study, how will we protect your privacy?**

Federal law requires Mass General Brigham 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:**

- Mass General Brigham 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 Mass General Brigham who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)



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- The Mass General Brigham ethics board that oversees the research and the Mass General Brigham 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. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. 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. The sponsor has agreed that it 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 Mass General Brigham, 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.

**Research Tissue Bank**  
**Version Date: November 2022**

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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.

Subject Name:

Date of Birth:

Subject

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

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Print Name

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Signature of Study Doctor or Person Obtaining Consent

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Date/Time

### **Statement of Person Giving Informed Consent and Authorization**

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

### **Signature of Subject:**

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

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Print Name

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Subject Signature

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Date/Time

Consent Form Version: 10/16/2024