

# Partners HealthCare System Research Consent Form

“Short” Tissue Repository  
Version Date: January 2019

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Protocol Title: Link My Heart - Brugada Project

Principal Investigator: Steven A. Lubitz, MD, MPH

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Description of Subject Population: Subjects, 21 years old or older, with a diagnosis of Brugada syndrome.

## Collection of Samples and Health Information for Research

### 1. What is the purpose of this research?

The Brugada Project is a research study that will collect and analyze genetic and health information from people with Brugada syndrome. It is part of a larger initiative called Link My Heart, which studies other genetic arrhythmias. The purpose of this research is to help scientists understand how arrhythmias that predispose to sudden cardiac death, such as Brugada syndrome (SCD), are affected by genes and other factors. We hope this can help develop ways to better prevent SCD as well as diagnose and treat these genetic arrhythmias.

We will collect, process, and store saliva samples in a research tissue bank located at the Broad Institute, a not-for-profit biomedical research institute. A research tissue bank is a place to store biological samples, such as saliva, that are linked to health information, and are used for scientific research.

Your sample will be stored until researchers need them to do research. Your saliva sample contains genetic information called DNA. Genes are parts of the DNA code that contain instructions for how cells in our bodies work and grow. We will study your DNA through a technology called “sequencing”. Gene sequencing is a way of reading the DNA to find changes in genes that may impact the way your cells behave, which might contribute to different types of health conditions and disease.

Tissue samples in this bank, which is located at the Broad Institute, will be used mainly for research on genetic mechanisms leading to Sudden Cardiac Death (SCD) and to help improve

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health results among patients and family members at risk for SCD. There is also a “Fact Sheet” that expands on the consent form to provide definitions and additional information.

Taking part in this research study is up to you. Your decision won’t change the medical care you receive within Partners, MGH, or your medical care giving institution 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.

If you have any questions before you sign this consent form or after you join the study, you can contact the tissue bank staff at 617-714-7560 from Monday - Friday 9 am – 5pm. The person in charge of the tissue bank is Dr. Steven A. Lubitz, MD, MPH.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. Partners Institutional Review Board is the IRB for this study.

If you want to speak with someone **not** directly involved in the study, contact the Partners Human Research Committee at 857-282-1900. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

## 2. What will happen in this study?

- We will ask you to complete questionnaires about your medical health history and your family medical health history on our online portal.
- We will ask that you collect a saliva (DNA) sample at home. We will send you a kit and instructions so you can collect the sample and mail it back to us in a self-addressed and pre-paid package.
- We will ask for your permission to obtain and access your medical records now and in the future to update your health information. We will ask you to provide information about your health care provider and sign a medical release form.
- We will collect specific information about you and your medical history from your medical records and store your health information in the study database.
- 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 arrhythmias or other conditions that may be related to sudden cardiac death (SCD).

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- We may call and/or email you to get additional information. For example, to ask if you would be willing to sign any additional documents that your hospital(s) may require in order to obtain your medical records, clarification of your medical history details, reminders to complete questionnaires, notification of additional protocols). We may also contact you in the future to ask if you are interested in joining other research studies.

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

- Your saliva (DNA) sample and information will be used mainly to study arrhythmia or other conditions that may predispose to sudden cardiac death, as well as many other diseases and conditions.
- We may perform different types of biological and genetic research with your sample. Genetic research may include looking at some or all of your genes and DNA to see if there are links to your health condition or to other conditions.
- We may share your samples, your DNA, genetic 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 and others, so that researchers from around the world can use them to study many conditions.

### 4. 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. The researchers involved in this study 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 the researchers 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.

You can choose to get a newsletter that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about Brugada syndrome and other related conditions. We may also publish what we learn in medical journals. In the future, when research results are published, they may show that certain groups (for example, racial or ethnic groups, or men/women) have genes that are associated with increased risk of a disease. If this happens, you may learn that you are at increased risk of developing a disease or condition.

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## 5. What are the benefits?

You will not directly benefit from research conducted on your samples stored in the tissue bank. We hope that research using the samples and information will help us understand, prevent, treat, or cure diseases.

## 6. Will you be paid for your samples?

You will not receive payment for your samples.

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.

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

There are no costs to you to participate in this tissue bank.

## 8. How are your samples and health information stored in the bank?

Your privacy is very important to us and we take a lot of steps to protect it. Staff at the bank, which is located at the Broad Institute, will assign a code number to your samples and health information. We will remove information that could easily identify you such as your name and date of birth and replace them with a unique code number before we share your health information with other researchers. We encrypt (scramble) your information when we store it, so it is hard for unauthorized people to read. The key to the code that connects your name to your samples and information will be stored securely.

## 9. Which researchers can use your samples and what information about you 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

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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 in this research study. 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.

## 10. How long will the bank keep your samples and information?

We will store your samples and information indefinitely.

## 11. Can you stop allowing your 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 tissue bank staff in writing.

Link My Heart  
The Broad Institute of MIT & Harvard  
415 Main St.  
Cambridge, MA 02142  
United States

## 12. What are the risks?

- 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.

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- There is a risk that information about taking part in genetic research may influence insurance companies and/or employers regarding your health.
- 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.
- Email communication is not encrypted and not secure and could result in the unauthorized use or disclosure of your information outside of this project. We will protect your privacy by not sharing medical information, diagnoses, or protected health information with you over email.

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

Federal law requires Partners 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:**

- Partners 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 Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners 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

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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)
- 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)
- Other: The Broad Institute staff involved in this study

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 Partners, 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.

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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.

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

### **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.
- By participating in this study, I agree that my data may be used for different types of health, medical, or biomedical research.

### **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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First Name

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Last Name

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Signature of Subject

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Date

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