Permission to Take Part in a Human Research Study

Title of Research Study: HeartShare Registry

Principal Investigator: Sanjiv J. Shah, MD

Supported by: This research is supported by National Institutes of Health (NIH)

Financial Interest Disclosure: None

If your doctor is also the person responsible for this research study, please note that s/he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have been diagnosed with and/or receive treatment for heart failure or may be at risk for heart failure. Alternatively, you may have no risk factors at all. Our research team is working to better characterize why people develop heart failure and how people feel when living with heart failure. Many people living with heart failure have significant symptoms that limit their ability to perform daily activities. If we are better able to identify early abnormalities that may be present, we may be able to minimize the risk for heart failure or improve quality of life and outcomes once people develop heart failure.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to learn more about what causes heart failure, which is a medical condition in which the heart does not keep up to the demands of the body, resulting in shortness of breath and swelling. People who have early-stage heart failure or are at risk for heart failure may not know that they have heart failure because they feel well. Some people who have heart failure may experience many symptoms and

some experience very few symptoms. HeartShare is studying why some people develop heart failure while others do not. In addition, HeartShare aims to better categorize heart failure into subtypes that can be targeted with specific treatments. In order to learn this information, the study team is recruiting people who do and or do not have heart failure. For this research, the study team will send you surveys every few months to ask about your health. The study team will also send you information on participating in additional study opportunities. You will be able to choose to participate in these additional opportunities or not as they arise.

How long will the research last and what will I need to do?
We expect that you will be in this research study for up to 5 years.

You will be contacted by phone or via an online survey in the Eureka app every 6 months to ask about your demographics, health, and family history. We will also ask you to complete a 3-question survey every month, and we will perform short assessments and questionnaires every 6 months remotely. These visits can be done over the phone or through our online data portal.

We'll notify you via push notification on your smartphone, email, and/or text message when new survey questions or other study activities are open to you. You will have the option to participate in additional study opportunities, including connecting your smartphone GPS, connecting your health records to share with the study team or connecting wearable devices, sensors, or other apps. You will be able to choose to participate in these additional opportunities or not as they arise.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
Some participants may find answering personal questions about sensitive topics (behavior, medical conditions, or lifestyle) to be a bit uncomfortable. As with any mode of electronic participation, there is always a small risk of loss of privacy. We'll always do everything we can to protect your data, but no app or study can ever be perfectly safe.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

HeartShare is not intended to provide medical care or interfere with your relationship with your own health care provider. If you do not have your own health care provider, you can be referred to one if you would like.

Permission to Take Part in a Human Research Study

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-503-2515.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Permission to Take Part in a Human Research Study

How many people will be studied?
We expect up to 10,000 participants will be enrolled in this study across the United States.

What happens if I say "Yes, I want to be in this research"?

1. We will ask you to fill out surveys about your health. We wish to track long-term health outcomes for patients enrolled in this registry. **This is a completely remote study (no in-person visits).** We'll send you surveys at the time of enrollment and every 6 months to ask about your demographics, health, and family history. We will also send a short monthly survey (3 questions) for updates and changes to your health. You can take the surveys on your smartphone with the Eureka app, on a computer with our web portal, or by talking on the phone with someone from the study team. If you have a smartphone, and only if you choose to do so, we'll also ask your permission to access your smartphone's geolocation (GPS) and activity data so we can determine if you are hospitalized during this study and ask questions related to your hospitalization. You will be asked this question from within the Eureka app after you sign this consent, and after you download and activate your login information in the Eureka app.

We anticipate most participants will spend a total of 2-3 hours per year completing surveys and other activities for the HeartShare study over an entire year.

2. You will have the option to participate in additional study opportunities, including connecting your smartphone GPS, connecting your health records in the Eureka app and sharing those records with the study team or connecting wearable devices, sensors or other apps. You will be able to choose to participate in these additional opportunities or not as they arise. These are optional components of the study, and you will be asked in the Eureka app whether you want to participate in these components or not. You can say no to these optional study opportunities and still participate in the HeartShare Registry.

3. We will get some information from other places in addition to the Eureka app. Taking part in the HeartShare Registry does not require any special study visits or trips to your doctor, yet to be sure we get a complete picture of your health, we will get certain information from your medical records from places where you receive health care. We will get information from past health records from 2006 until now. Examples include information about your health problems, health care visits, hospital stays, medical procedures and tests, images, and lab results. The information from your health record will be recorded and sent along other the other information you provide us as described in the "What happens to the information collected for this research" section below.

4. Some participants will be invited to participate in a part of the study with in-person testing. This is called the Deep Phenotyping Cohort of the HeartShare study. Participating in this part of the study would require extensive in- person testing. If

invited to the Deep Phenotyping Cohort, you will have the opportunity to go over all of the study activities before consenting to participate. It will be your choice to participate in the in person testing and you will be provided with a separate consent to participate.

5. As part of the HeartShare Study, you may also be contacted and be invited to participate in other research studies. We'll let you know when there are other studies you might qualify for by push notification on your smartphone, email, and/or text message. You will be provided with additional information and additional consents for those studies. You will have the opportunity to learn about those studies before deciding to participate. It will be your choice whether to participate in those additional studies or not.

Permission to Take Part in a Human Research Study

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?
This research may hurt you in the following ways:

- Cognitive testing: Questions that you will be asked may cause mental or emotional discomfort.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you. However, depending on your mobile phone plan, you may be charged for text messages you receive from us.

As a thank you for your time and effort, you will be enrolled in a quarterly (that is, every 3 months) raffle drawing for participating in the HeartShare Registry. You will receive one raffle entry for completing the baseline surveys when you join the study, and you will receive an additional raffle entry for completing 3 monthly surveys after joining. This means if you complete the baseline surveys and the monthly survey for 3 months in a row, your name will go into the raffle drawing twice. Participants' names will be drawn from the raffle quarterly and each winner will receive a $100 Amazon gift card. If your name is randomly chosen, within the week of the raffle drawing, you will receive an email with the Amazon gift card code. Additionally, a study research assistant will call you to confirm that you received the email with your gift card code.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research and the Office for Research Integrity, and members of the Institutional Review Board (a committee responsible for the ethical oversight of the study)

Representatives of our study sponsor, the National Institutes of Health and the National Heart, Lung and Blood Institute, The Office for Human Research Protections (OHRP), and other researchers (the Principal Investigators of the HeartShare Clinical Centers study at the Massachusetts General Hospital/Brigham and Women's Hospital, Mayo Clinic, University of Pennsylvania, University of California-Davis, and Wake Forest University, the staff of the HeartShare Data Translation Center and other HeartShare staff involved with this study.

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We'll always do everything we can to protect your data, but no app or study can ever be perfectly safe from hacking. Your information will be transmitted and stored using state-of-the-art security systems similar to those that protect websites used by banks and electronic health record systems. Specifically, the Eureka Research Platform is hosted on Amazon Web Services (AWS), a cloud-based server system and computing services. These systems and services are compliant with the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA). All research data are stored behind a secure firewall, guarded by intrusion detection software, and encrypted at rest and in transit in our Amazon Virtual Private Cloud.

Your information will be transmitted and stored using very secure systems, including BioData Catalyst, a secure, encrypted, web-based "cloud" that is a repository for research-related data. All data in BioData Catalyst will be de-identified. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. You are participating in a research project supported by the Eureka Research Platform, which maintains a Privacy Policy and Data Security Measures. You will be notified of any changes in this policy.

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 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. For example, you may give them permission to release information to insurers, medical providers or any 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.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by

current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

Commercial use of data and samples:
Researchers from private companies, such as those that develop diagnostic lab tests or treatments for diseases, may request access to your study information. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, social security number, address, etc.

HeartShare data may lead to inventions or patents in which private companies or the universities conducting HeartShare may participate and may benefit.

Neither you nor your family would benefit financially from discoveries made using the information that you provide.

HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law

or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Other researchers who are approved members of the study team
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institutes of Health who are funding the study
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

PI's Name: Sanjiv Shah, MD
Institution: Northwestern University Feinberg School of Medicine
Department: Medicine
Address: 676 N. St. Clair, Chicago, IL 60611

Permission to Take Part in a Human Research Study

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Permission to Take Part in a Human Research Study

Signature Block for Adult Capable of Providing Consent:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant