RESEARCH CONSENT FORM
Individual Site Information
Part 2 of 2

Site Name: Stanford University School of Medicine
Study Title: Initial Development of a Digital Decision-Making App for Implantable Cardioverter-Defibrillator Decisions (SU sIRB)
Stanford IRB Application Number: IRB# 79108
Site Principal Investigator: Randall S. Stafford, MD, PhD
Site Principal Investigator Contact Information: rstafford@stanford.edu, 650-492-9280
Other Study Contact(s): N/A

Introduction: This study will be conducted at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the individual site information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Site-specific Enrollment: We are hoping to recruit up to 100 participants from the Stanford site.

Conflict of Interest: The site investigator, Dr. Randall Stafford, reports no relevant conflicts of interest.

Costs: There is no cost to you for participating in this study, other than basic expenses like transportation, computer costs, and the personal time it will take to participate in the study visits.

Research-related injury: All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you agree to this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before agreeing to it.

What is the purpose of this research study and how will my health information be utilized in the study?

This study is developing digital tools that will help people better understand implantable cardioverter-defibrillators (ICDs), including their benefits and drawbacks. To develop and test these digital tools, we are asking people with heart failure to participate in interviews, focus-groups, and surveys.

Do I have to agree to this authorization form?

You do not have to agree to this authorization form. But if you do not, you will not be able to participate in this research study. Agreeing to the form is not a condition for receiving any medical care outside the study.

If I agree, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Randall Stafford, MD, PhD at rstafford@stanford.edu.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to your name, age, gender, and medical information.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Randall Stafford, MD, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)
- The National Institutes of Health (NIH), the research sponsor.
- Other state, federal, and international agencies or committees

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2035 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

For Questions, Concerns or Complaints about the study, Contact: Stanford Site Director, Dr. Randall Stafford at 650-492-9280 or rstafford@stanford.edu.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Participant Bill of Rights
As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form

The extra copy of this signed and dated consent form is for you to keep. **Do not sign below unless you have received and read the Part 1 consent document.**

Consent Signature Lines:

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness