STANFORD UNIVERSITY Research Consent Form Part 1 of 2

Protocol Director: Randall S. Stafford, MD, PhD

Protocol Title: Initial Development of a Digital Decision-Making App for Implantable Cardioverter-Defibrillator Decisions (SU sIRB)

IRB Use Only
Approval Date: Monthname dd, 2025
Expiration Date: Monthname dd, 2026

IRB# 79108

DESCRIPTION: You are invited to participate in a research study on decision-making in heart failure. The research 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. You will be asked to participate in one or more of these activities. This research study is looking for a total of 100 people to be enrolled. Audio or video recording may be used to more accurately interpret your input. You give your consent for your video or audio recordings to be used for the described purposes. Such recordings, if any, will be destroyed once the digital decision-making tool is fully developed.

FUTURE USE OF PRIVATE INFORMATION: Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research. Identifiers might be removed from identifiable private and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

TIME INVOLVEMENT: Your participation may vary from approximately 10 to 60 minutes depending on the type activity.

RISKS AND BENEFITS: The risks associated with this study are minimal and involve inadvertent loss of confidentiality despite our best intentions to protect your personal information. The benefits which may reasonably be expected to result from this study are the potential for you to better understand heart failure and implantable cardioverter-defibrillators (ICDs). **We cannot and do not guarantee or promise that you will receive any benefits from this study.** Your decision whether or not to participate in this study will not affect your medical care.

PAYMENTS: You will receive reimbursement to partly compensate you for your time and effort. Depending on the activity, payments may vary from $10 to $50.

SPONSOR: The National Institutes of Health (NIH) is providing financial support for this study.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your **participation is voluntary** and you have the **right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise**

entitled. **The alternative is not to participate.** You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

CERTIFICATE OF CONFIDENTIALITY: This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the U.S. federal agency sponsoring the project that is needed for auditing or program evaluation by NIH, the project sponsor. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WITHDRAWAL FROM STUDY: The Protocol Director may withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION: *Questions:* If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact

Protocol Director, Dr. Randall Stafford at 650-492-9280 or rstafford@stanford.edu. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

For study details that apply to your enrollment site, continue reading part 2 of the consent form.