PERMISSION FOR RELEASE OF MEDICAL RECORDS FOR RESEARCH

PRINCIPAL/OVERALL INVESTIGATORS: **Christine M. Albert, M.D., M.P.H.**
PROTOCOL NUMBER: **2007-P-000840**
PROTOCOL TITLE: **PRE-DETERMINE Biologic Markers and MRI SCD Registry Study**

Please read the following release of medical records form and sign on the reverse side. Your signature will indicate that you have read and understood this document as well as provide permission for us to obtain medical records pertaining to your: Implantable Cardiac Defibrillator (ICD) Implantation and Device Interrogations

Federal law requires that we, as researchers, health care providers, and physicians' networks, protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). In the PRE-DETERMINE Study, your "protected health information" will continue to be used and shared with others as explained below. If you agree to the described uses within our group (the Brigham and Women's Hospital and Harvard Medical School) and to the sharing of your protected health information with collaborators outside our group, then after reading this entire document, please sign your name at the end of this form. This confidentiality statement is an updated and expanded version of the confidentiality section contained in the consent form you signed at the beginning of the PRE-DETERMINE Study.

1. Why will my protected health information be used or shared with others?

- To conduct and oversee the research being conducted in the PRE-DETERMINE Study;
- To ensure the research meets legal, institutional, and accreditation requirements; and
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm).

A copy of our institution's Notice for Use and Sharing of Protected Health Information, which provides more information about how our hospital and its affiliates use and share protected health information, can be found on the following website: http://www.partners.org/disclaimer.html.

2. With whom may my protected health information be shared?

All reasonable efforts will be made to protect the confidentiality of your protected health information, which may be shared with the following others for the reasons noted above:

- The Brigham and Women's Hospital, Harvard Medical School, and their affiliated researchers and entities participating in the research will use and share your protected health information. In addition, the Brigham and Women's review board that oversees the research and its affiliated staff who have a need to access this information to carry out their responsibilities (i.e., oversight, quality improvement) will be able to use and share your protected health information.
- Outside individuals or entities that have a need to access this information to perform functions on behalf of the Brigham and Women's Hospital and its affiliates (i.e, collaborators reviewing and participating in research).
- Other researchers and medical centers participating in this research, if applicable.
- Federal and state agencies (i.e., the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections) or other domestic or foreign government bodies if required by law.
- A data and safety monitoring board organized to oversee this research, if applicable.
- We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may re-disclose it, so we share this information only if necessary, and we use all reasonable efforts to request that those who receive it take steps to protect your privacy.

3. What protected health information about me will be used or shared with others during this research?

- Existing self-reported information from questionnaires and previously released medical records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires.

(Over)

4. For how long will my protected health information be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process, during which information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight, or other purposes.

5. Statement of privacy rights:

- You have the right to withdraw your permission for the researchers and participating entities to use or share your protected health information. We will not be able to withdraw all of the information that already has been used or shared with others to carry out the research or any information that has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you want to withdraw your permission, you must do so in writing by contacting the researcher listed below as the Study Contact.
- You have the right to choose not to sign this form, which will prevent us from obtaining and using information from your medical records related to the diagnosis and/or procedure you have reported. Choosing not to sign will not affect your present or future care at any healthcare facility and will not cause any penalty or loss of benefits to which you are otherwise entitled.
- You have the right to request access to your protected health information that is used or shared during this research and that relates to your clinical treatment or billing status, but you may access this information only after the study is completed. To request this information, please contact the researcher listed under Study Contacts below.

PLEASE COMPLETE THE FOLLOWING INFORMATION AND SIGN BELOW:

Implantation and device interrogations: Implantable Cardiac Defibrillator (ICD) Date of implantation: _____ - Present

Name of hospital/physician where ICD was implanted: _____

Address of hospital/physician: _____ City: _____ State:_____ Zip:_____

Name of cardiologist/electrophysiologist following ICD: _____

Address of physician: _____ City: _____ State:_____ Zip:_____

YOUR FULL NAME AT THE TIME OF TREATMENT: _____

If your physician is able to remotely monitor your ICD from home for heart rhythm disturbances, we would like to share your ICD model and serial number with the company that manufactured your device in order to collect valuable information that may have been detected and treated by your ICD over the course of the study. This information is critical to be able to determine what factors place patients at higher risk for heart rhythm disturbances.

Do you grant us permission to share your ICD model and serial number with the device manufacturer? _____ Yes _____ No

By my signature below, I hereby grant permission to Dr. Christine M. Albert, Director, Center for Arrhythmia Prevention, Brigham & Women's Hospital, 900 Commonwealth Avenue, 3rd Floor, Boston, MA 02215, to obtain records pertaining to my ICD device, which includes implantation, device readings (office visits and/or remote monitoring), and devise removal (if applicable) for the duration of the study. (COPY VALID AS ORIGINAL; VALID FOR THE DURATION OF THE STUDY).

_____
Participant's signature **Date**

_____
Print name

OR

Signature of individual authorized by the subject to make health care decisions:

_____
Court-appointed Guardian/Health Care Proxy **Date**

_____
Family Member/Next-of-kin **Relationship**

STUDY CONTACTS:

Christine M. Albert, M.D., M.P.H., Principal Investigator
1-877-718-8003 (toll-free)

Mass General Brigham IRB Representative
(857) 282-1900