The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Same Day Subcutaneous ICD And Send Home (DASH)

Principal Investigator: Toshimasa Okabe, M.D.

Sponsor: Boston Scientific Corporation.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The number of subcutaneous implantable cardioverter-defibrillators (S-ICD) implants is increasing in the United States. At the Ohio State University Medical Center, we have implemented an institutional protocol to allow same-day discharge following S-ICD implantation, and S-ICD implantation is currently performed on an outpatient basis. Across the country, however, many S-ICD patients are admitted overnight for observation and pain management

The purpose of this study is to evaluate our current practice of same-day discharge and pain management for patients receiving an S-ICD device. This study will help gain a better

understanding of the success of discharging patients the same day after their S-ICD implant procedure.

2. How many people will take part in this study?

Up to 50 patients will be enrolled in the study at Ohio State University. Patients who qualify based on the studies requirements will be invited to participate.

3. What will happen if I take part in this study?

This is an observational study to gather information to evaluate the success of same day discharge and pain management of patients after S-ICD implantation at Ohio State University. Collection and review of your S-ICD medical information will be the only research activity for this study. You will receive the same care before, during, and after S-ICD implantation, including follow-up phone calls, regardless of whether you take part in this study.

The hospital lab staff will explain your S-ICD implant procedure and review the risk of the procedure to you as is their normal practice. You will be required to sign the hospital Cardiac Implanted Electronic Device consent form.

To participate in this study; you will also be asked to sign this consent to allow the clinical data be collected from you and from your doctor. If you decide to participate in the study, you will have your standard of care device procedure and your medical information will be gathered from you and your medical records.

The medical information gathered for the study will be

- Information from the day of, and after your implant; this includes pre- and post-device implant procedure information
- The time it took from the beginning of your recovery; to the time of your discharge from the recovery unit.
- We will also collect from your records your recovery unit pain evaluation information using the 0-10 Numerical Pain Rating Scale (NPSR).
- The information you provided over the phone per the follow up calls to check how you are doing on day1, day 3, and 2 weeks after your implant; where you will be asked questions from the Pain Perception Questionnaire and the number of painkillers you've used since being discharged home
- Information will be collected from the 30 day follow up visit at the OSU Device Clinic, where you will again be asked questions form the Pain Perception Questionnaire, and if you have been readmitted to the hospital since the initial procedure.

Furthermore, your medical records will be reviewed to obtain information on any outcomes and complications you have after your implant; this will also be collected for this study. None of this information will be used to manage your care, but will be analyzed later.

4. How long will I be in the study?

Your participation in this study will end after your 30 day visit at the OSU device clinic.

5. Can I stop being in the study?

You do not have to participate in this study to have your S-ICD procedure. If you decide after the procedure that you want your data removed from that being reviewed, you can contact the study investigator to remove your procedure data. Again, you will receive the same care before, during, and after S-ICD implantation, including follow-up phone calls, regardless of whether you take part in this study.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is a small risk of loss of confidentiality when you participate in an observational study, In the event of any publication or presentation that results from the research, no personally identifiable information will be shared.

You will be asked by the lab staff at the hospital to sign a separate Informed Consent Form for the S-ICD implant procedure, and they will discuss all of the risks associated with the S-ICD procedures. There are no additional medical risks that are associated with this study above the standard risk of the S-ICD implant procedure that the hospital staff explained to you.

Again, the data collected for this study will be analyzed at a later date, and will not change the usual approaches used in your procedure for managing your health by your doctor.

7. What benefits can I expect from being in the study?

There will be no direct benefit to you other than closer examination of the benefits of same day discharge after your procedure, but it is hoped the results of the study will help guide physicians across the country and around the world to better care for patients when doing an S-ICD procedure.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You are being asked to participate in this study because you are already scheduled to undergo S-ICD procedure and you may choose not to participate in this study.

9. What are the costs of taking part in this study?

There will be no cost to you to participate in this study. You and your insurance company are responsible for all costs that are normally associated with your procedure and treatment.

10. Will I be paid for taking part in this study?

You will not be paid to participate in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects' research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact ***Toshimasa Okabe, M.D., 473 W. 12th Avenue, Suite 200, Columbus OH 43210; phone (614) 293-4967.***

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***HIPAA Privacy Officer, 600 Ackerman Road, Suite E2140, Columbus, OH 43201.***

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact ***Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.***

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Toshimasa Okabe, M.D., 473 W. 12th Avenue, Suite 200, Columbus OH 43210; phone (614) 293-4967.***

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM **Date and time**
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM **Date and time**
Printed name of witness	**Signature of witness**
	AM/PM **Date and time**