IRB APPROVED
AS MODIFIED
Oct 30, 2023

UNIVERSITY OF CALIFORNIA, IRVINE
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: LUX-Dx Heart Failure Sensors in an Insertable Cardiac Monitor System Clinical Study (Short Title: LUX-Dx TRENDS)

PROTOCOL NO.: C2118
WCG IRB Protocol #20204282
UCI IRB# 945

SPONSOR: Boston Scientific

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STUDY RELATED PHONE NUMBER(S): 714-456-6699 (24 hours)

RESEARCH SITE ADDRESS(ES): UCI Health
101 The City Drive South
Orange, CA 92868

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

Introduction
Insertable cardiac monitors (ICMs) are small devices implanted under the skin that are commercially used for the detection of abnormal heart rhythms and long-term monitoring.

ICMs have the capability of wirelessly transmitting data about your heart rhythm to your study doctor. We are asking you to participate in an investigational research study looking at various sensors which offer added Heart Failure (HF) diagnostic (not providing therapy) features to accompany our standard ICM system known as LUX-Dx. The ICM, with or without these sensors, is intended for diagnostic purposes only. This consent form provides information on the procedures, benefits and risks involved in the LUX-Dx TRENDS study. The study doctor or his/her representative will also talk to you so you can decide if you want to take part in the study. Please read this form carefully so you can decide if you want to take part in the study. Ask the study doctor or his/her representative any questions you may have about this study. You do not have to be in the study. Your medical care will not change in any way if you chose to not participate or you decide to participate then leave at a later date. Please take as much time as you need to make your decision.

Why are you being asked to take part in this research study?
You are being asked to participate in this study because medical tests show you have heart failure. Heart failure is a condition that makes the heart muscle weak and the heart cannot pump as much blood as the body needs. We have added the sensors to the ICM to determine whether they can provide doctors who treat patients with similar conditions with additional information to help analyze their heart failure condition.
This study will gather information about the sensors.

Why is this research study being done?
Boston Scientific, the sponsor of this study, has developed a program called HeartLogic™. This program uses multiple sensors to monitor heart failure and is currently used within other implanted cardiac devices. These sensors include the following in figure 1 below.

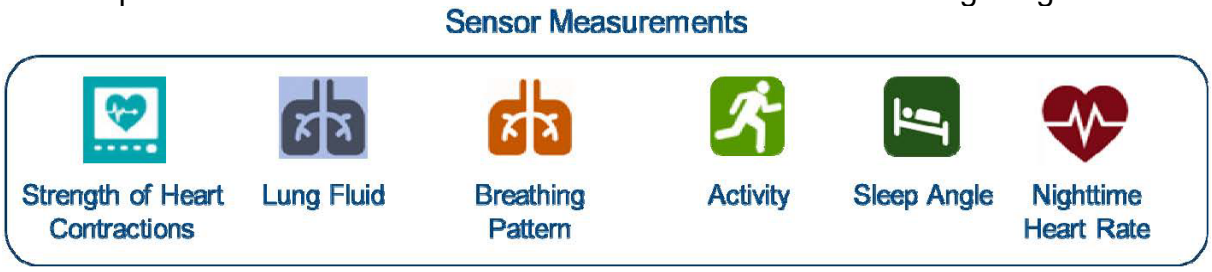

Figure 1. Sensors Available in HeartLogic™

Boston Scientific currently has the HeartLogic sensors active in the implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices which provide therapy to help correct abnormal heart rhythms in certain patients. Boston Scientific would like to add some of these sensors to an investigational version of the ICM. What makes it different from the commercial ICM system is the device has been programmed to capture and transmit the sensor data that have not previously been captured by the commercial system. The use of these sensors in the ICM system has not been approved by the FDA and is considered investigational (experimental).

Approximately 290-525 subjects are expected to participate in this study. Up to 65 study sites will participate in the United States. Enrollment is expected to be completed in approximately 24 months; therefore, the total study duration is estimated to be

approximately 4 years. The study duration for each implanted subject will vary depending on the battery longevity of their study device but is expected to be approximately 18 – 20 months.

What will happen to you while you are in this research study?
If you agree to be in this study and sign this informed consent form, you will undergo the investigational ICM implant. You will be provided with a mobile monitor which is similar to a cell phone with a downloaded application (app) named myLUX. The myLUX app will monitor your heart rhythm and alert your study doctor if you experience an abnormal rhythm and allows data to be transferred from your device to your study doctor and to Boston Scientific. Data is transferred to the app using wireless, Bluetooth technology. The data is uploaded to the LATITUDE Clarity system; a web-based portal used to review your data. The mobile monitor should be kept at your bedside, carried with you when you travel overnight and remain charged.

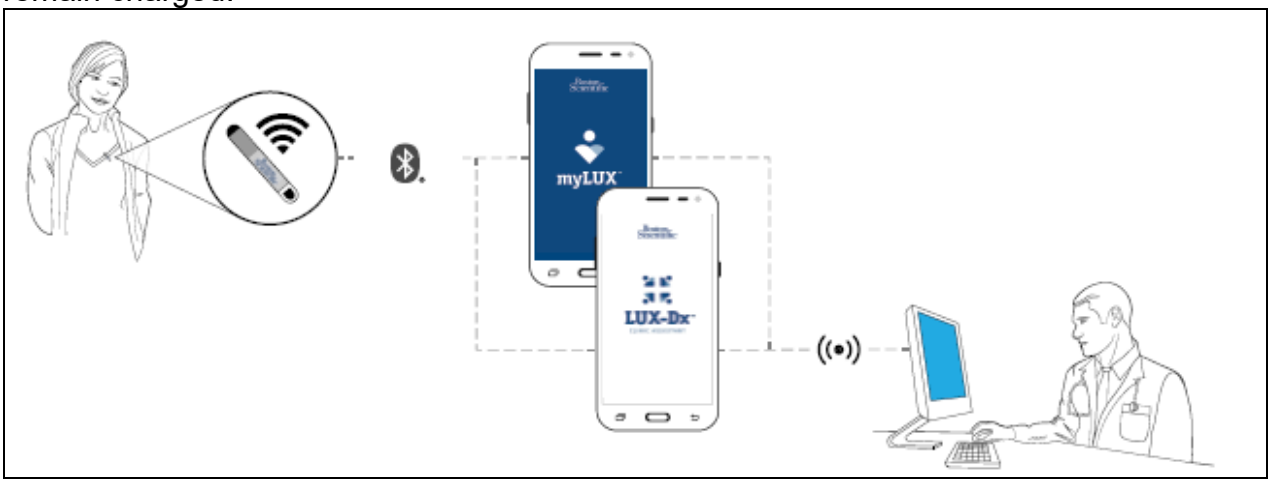

Figure 2 LUX-Dx ICM Device and Mobile App - MyLUX used by You (Patient) and LUX-Dx Clinic Assistant used by Your Study Doctor

In addition, the myLUX app will also communicate the investigational sensor data directly to Boston Scientific via LATITUDE Clarity; your data will not include any personal information and your study doctor will not have access to this data.

You must use the mobile monitor and myLUX app as instructed for device data transmission and monitoring. You are requested to work with your study doctor to resolve any connection issues if your device does not transmit device data for monitoring.

Approximately 2 months after your ICM implant procedure, you will be asked to visit your study doctor's office to attach a wearable cardiac monitor patch on your chest area for about 2 weeks. The application of the patch may include the use of an over the counter electrode gel or adhesive dressing (such as skin prep products, Tegaderm™ transparent film dressing, or other similar commercial products). The use of the wearable cardiac monitor patch in this study is also investigational. During the same visit or in a separate visit, you will be asked by your study doctor or representative to participate in one or two sub-studies. A sub-study is a smaller study within the LUX-Dx TRENDS study where additional information

is collected through specialized testing. These two additional sub-studies include an echocardiogram and an exercise test. You will be asked to complete a separate informed consent by your study doctor for each of these sub-studies. You may participate in one or both of these sub-studies. If you decide not to participate in any sub -study that is still open for enrollment, you will not be able to participate in the main study.

You will be followed in the study until your study doctor is alerted by LATITUDE Clarity that your ICM device's battery life has run out. The average amount of battery life for the ICM's used in this study is estimated to be about 1 year and 10 months. During your time in the study, your study doctor will review your medical records every 6 months and contact you to make sure that everything is okay. While you are participating in this study, it is important to tell your study doctor if you have any planned or unplanned visits to the hospital for any reason, including planned or unplanned visits, admission to the hospital for heart failure, and/or if you have been treated with an IV medication for your heart failure in the emergency room, urgent care or your clinic. These medical events are a very important part of the study. When possible please use your study doctor's office and hospital for your heart failure treatment and/or for any hospitalization.

You will be expected to visit your study doctor's office, or speak with the study doctor or representative, as listed in Table 1 below.

Table 1. Patient Visits and Activities

When		Tests and Evaluations to be Conducted
Enrollment	Baseline Visit (Start of the study)	• Obtaining your informed consent to participate in the study • Heart failure assessment (signs and symptoms) and physical exam • Past medical history review
		In-clinic
Implant	Within 30 days post-enrollment	• LUX-Dx ICM insertion into the body • A blood draw (about 1-2 teaspoons) • Enrollment in LATITUDE Clarity and myLUX mobile kit orientation • Review any adverse events that may have occurred with the implant of the LUX-Dx ICM • Diagnostic sensor programming of your ICM by Boston Scientific representatives
		In-clinic or In-hospital
Post-implant Follow-up visit and Sub-study visit	2 months post-implant (+/- 30d)	• Adverse event review • Heart failure assessment (signs and symptoms) and physical exam • 2-week Wearable Cardiac Monitor attachment • Sub-study participation (if applicable)

		In-clinic
6, 12, & recurring 6-Month Follow-up Visit	6, 12, & recurring 6-month post implant (+/- 14d)	• Remote adverse event review and patient status review (telephone contact)
		In-clinic or by Virtual Health Visit
Final Subject Contact	2 years post implant (+/- 30d) or until ICM battery life is expired	• Remote adverse event review and final patient status review (telephone contact) • End of study data collection • Procedure to remove device**
		In-clinic or by Virtual Health Visit

*The final patient enrolled in the study will have their final subject contact 2 years after ICM implant even if their ICM battery life has not expired. **Will occur only if your study doctor determines that removal is medically necessary.

What are the Potential Risks by participating in this study?
If you are enrolled in the study and receive the investigational ICM used in this study, you are exposed to the same risks as patients outside of this study who receive the same or other similar commercial ICM device(s). Note: The battery in the investigational device will deplete faster than the battery in the commercial device by approximately 15 months for an estimated total battery life of 1 year and 10 months. The risks associated with the ICM device implant and participating in the study are listed in Table 2 below. Your doctor may inform you regarding any additional known risks related to the devices used in the study. There may also be additional risks which are not known at this time.

Table 2. Risk Associated by Implanting the ICM Device and Follow-up Procedures

- ICM Device location shifting or coming out from the skin
- Foreign body rejection (the body rejects the insertion of a medical device)
- Bruises or fluid under the skin
- Infection
- Skin irritation and allergic reaction from the adhesive or other skin-contacting materials used with study devices
- Pain, fainting, bruising or bleeding, and potential infection from study-required blood draw
- Temporary discomfort, allergic reaction, bruising or bleeding from local anesthesia administration.

What are the Risks of Being Pregnant in this research Study?
In addition to the known risks above, this treatment or procedure has not been studied in pregnant women and there may be additional unknown risks to you, your embryo, fetus or nursing infant. Notify your doctor immediately if you become pregnant while in this study.

Pregnant women and women who plan to become pregnant during this study will be excluded from this study.

What are Potential Benefits from being in this research study?
Potential benefits include helping scientists and your doctors learn more about the sensors in the investigational LUX-Dx ICM and heart failure monitoring. You may benefit from increased cardiac monitoring and care from your doctor during your study participation. However, it is possible you may not receive any personal benefit from participating in this study.

What alternatives do you have it you choose not to participate in this research study?
This study is being done to gather information. You do not have to participate in this study. Depending on your heart failure condition, you may be eligible to receive a device that provides therapy. Your study doctor will discuss with you the risks and benefits of any other devices that you are eligible to receive. If you choose to receive a therapy device, you will not be able to participate in this study.

What happens at the end of the study?
At the conclusion of the study, your doctor may want to remove the ICM through an additional procedure after the battery has depleted. After the device has been removed, you will be monitored for a period immediately after to assess for any adverse events related to the removal of your ICM. After you are discharged/recovered from this procedure (or if it is decided to let the ICM remain in your body), you will be done with the LUX-Dx TRENDS study and continue to be followed by your doctor per your normal medical care.

What are your rights?
Your participation is voluntary. There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you leave the study early. You may choose not to be in the study. You may withdraw from the study at any time. There will be no impact to the care you receive or any loss of benefits to which you are otherwise entitled if you decide to be in or decide not to be in the study. If you do not sign this form, you will not be allowed to participate in the study.

If you withdraw from the study at any point, your information that is collected up to the point may be used and may continue to be used. The study staff, Institutional Review Board (IRB) that oversees the research and Boston Scientific will continue to have access to your medical records to confirm the accuracy of your data collected during your time in the study.

Your study doctor may decide to stop your participation in the study if it is necessary for your safety or for other reasons. This may occur with or without your consent. If your study doctor stops your participation, you will be notified. The study may also be stopped by a regulatory authority such as the FDA, an IRB, or Boston Scientific, in which case you and your doctor will be notified.

If you are no longer participating in the study for any reason, you will still need to continue to have your device checked at your doctor’s office and followed by your doctor.

New information may come up during the study and it will be provided in writing in a timely manner. The new information may affect your decision to continue to be part of the study.

Depending on the new information, you may be asked to read and sign a new updated consent form for the study.

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

Who is funding the study?
The Study Sponsor is paying the facility listed on page 1 of this document for their participation in this study. This payment is compensation for the time and resources required for study administration and execution.

What tests or procedures will you need to pay for if you take part in this research study?
There is no cost to you or your insurer for your participation in this study.

You and /or your health plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

Will you be compensated for participating in this research study?
If allowed by your study site, you may receive a patient stipend for participating in the study that is intended to provide you with reimbursement for your efforts to attend study visits. Your study doctor will explain this to you.

For taking part in this research, you may be paid up to a total of $250. You will receive payment in the form of a direct deposit. If you do not complete the research study, you will be compensated prorated according to the study visits you do complete. Your study doctor will explain this to you. You may receive $50 following the post-implant office visit and $200 for completion of the sub-study, if enrolled.

What if you are injured from participation in this research study?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you feel you have been injured as a result of being in this study UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor Boston Scientific or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu.

If the study sponsor covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose.

What are your Legal Rights?
By signing this form, you are not giving up any of your legal rights or releasing the Study Doctor, study staff, Study Sponsor, hospital or their agents from liability for negligence.

What will happen if your device needs to be recovered?
In the event of your death while you are participating in the study, your study doctor will seek copies of your medical records regarding your death. This may include emergency room records and hospital records. This information will be used for research purposes and will be kept confidential. Your family will also be asked to allow for the removal of your ICM device if necessary for evaluation. Your family will not be charged for this procedure. If your family objects to the removal, your family's wishes will be honored.

Identification and the Advice of the Ethics Committee or Institutional Review Board
This clinical investigation and Patient Information and Consent Form has been reviewed and approved by the following Ethics Committee: WCG IRB.

What are the roles of the Boston Scientific Representatives in this study?
In this study, and at the request of your doctor, a representative of Boston Scientific who is obligated to maintain your privacy may:

- Provide technical expertise for the device that you will receive or, for the device testing that will be conducted.
- Be present at the implant, follow-up visits, or other study related testing at your doctor's request.
- Assist in the programming or testing of your device, under the direction of your doctor.
- Contact you directly.
- Be aware of how your device is programmed and your test results.

Please talk to your doctor if you have any questions about Boston Scientific representatives.

CONFIDENTIALITY, DISCLOSURE AND USE OF YOUR INFORMATION
Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the research team
- authorized UCI personnel
- the sponsor

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA
- Department of Health and Human Services (DHHS) agencies;
- governmental agencies in other countries;
- the University of California; and the Western Copernicus Group (WCG) IRB, Inc.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. If the results of this study are made public at meetings or in scientific journal articles, information that identifies you will not be used.

Medical Care

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your records. If necessary for your care, this information will be provided to you or your physician.

What happens if you withdraw from the study?

Your participation in the study is voluntary. You may choose not to be in the study. If you choose not to be in the study there will not be any negative impact to the care or treatment you receive or any loss of benefits to you.

In addition, if you withdraw from the study it may be necessary for the study sponsor to continue using the information collected about you up to the point of your withdrawal as allowed by this consent form. For example, the study staff, WCG IRB, Boston Scientific or its representatives, and applicable regulatory authorities will continue to have access to your original medical records to confirm your data collected during your time in the study is accurate. This information is important for study sponsors and regulatory authorities to identify potential patient and device safety issues. Finally, in order to confirm the safety of the device, regulatory authorities may request confirmation of your health status, including information about device clinical performance, effectiveness or safety, even if you have withdrawn from the trial or you do not continue to follow up with your study doctor as required in this form. By signing this consent form you agree to be contacted and/or to have your original medical records and public records accessed to confirm your health status.

OTHER ISSUES TO CONSIDER WHEN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials.

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

Investigator Conflict of Interest

The study team has reported no financial conflicts of interest.

Contact the research team listed at the top of this form during office hours for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Call the 24-hour number also listed on the top of this form at any time to report a research-related injury or a health concern possibly related to the study drug.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE, Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form and the "Research Subject's Bill of Rights" to keep.

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

If the research described in this form involves your protected health information (PHI), you will be asked to sign the UC HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information which is appended at the end of this form.

I agree to participate in the study.

_____ _____
Subject Signature Date

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent Date
(Individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Research Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study, you should contact the study team listed at the top of the consent form.

I can also contact the WCG IRB, Inc. which helps protect research study participants. I can reach the WCG IRB, Inc by calling 855-818-2289 from 8:00 AM to 5:00 PM, Monday to Friday. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write to WCG IRB, Inc., 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115. To get a copy of the bill of rights I may contact the research team or go to www.research.uci.edu/ora/forms/hrpp/ExperimentalSubjectBofR.doc

UCI IRB # 945

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): LUX-Dx Heart Failure Sensors in an Insertable Cardiac Monitor System Clinical Study (Short Title: LUX-Dx TRENDS)

Principal Investigator Name: Dawn Lombardo, DO

Sponsor/Funding Agency (if funded): Boston Scientific

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

- ☒ Entire Medical Record
- ☐ Ambulatory Clinic Records
- ☐ Progress Notes
- ☐ Other Test Reports
- ☐ Other (describe): (Description of Other Health Information)
- ☐ Lab & Pathology Reports
- ☐ Dental Records
- ☐ Operative Reports
- ☐ Discharge Summary
- ☐ Consultations
- ☐ Emergency Department Records
- ☐ Financial Records
- ☐ Imaging Reports
- ☐ History & Physical Exams
- ☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
_____I agree to the release of HIV/AIDS testing information.
_____I agree to the release of genetic testing information.
_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)—*required*

_____

Subject's Signature

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____

Witness' Signature

_____

Date