CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

I. STUDY TITLE: [Exactly as appears on study title page]

Sponsor:

Institution: Lancaster General Hospital
555. N. Duke Street
P.O. Box 3555
Lancaster, PA 17604-3555

Principal Investigator:

Co-Investigators:

II. PROTOCOL NUMBER & PROTOCOL DATE:

III. PRINCIPAL INVESTIGATOR AND RESEARCH TEAM:

To include names and phone numbers of all investigators and collaborators at Lancaster General Hospital.

IV. Include the following statement verbatim prior to the "Introduction" paragraph:

Doctors may ask patients to take part in a research trial of a new drug, device, or medical treatment. Before a patient agrees, the doctor or research staff must give the patient information about the risks and benefits of the study. The form you are about to read gives such detailed information. Once you understand the study, you can decide if you want to take part in it. If you do, you will need to sign this consent form. You will get a copy of the form that you sign.

V. INTRODUCTION:

√ To include statement that the study involves research or experimental procedures.

VI. STATEMENT OF PURPOSE:

Research objectives drafted in lay person's terms using sixth-grade vocabulary.

VII. NUMBER OF SUBJECTS INVOLVED:

State the total number of subjects expected to be enrolled in the entire study and the number at LGH.

VIII. PROCEDURE, LENGTH OF STUDY INVOLVEMENT, AND REQUIRED FOLLOWUP:

Describe in lay person's terms the protocol to be followed in the conduct of the research study, being certain to include a lay person's description of the protocol, the length of the study, the tests involved and visits to the doctor, and anything else involving the patient in terms of the study and follow-up.

Please include the following for SJM CRT device studies that require a passcode for interrogation by non-research personnel:
If someone other than the research staff tests your CRT device, the tester will see a warning message on the computer. The message tells the tester that your device is a study device. The tester will need to call St. Jude Medical for a password to continue, which may cause a brief delay in completing the test.

IX. BENEFITS:

Describe benefits to the subject and/or to others, which may be reasonably expected.

X. RISKS AND DISCOMFORTS:

- ✓ Side effects
- ✓ Material risks
- ✓ Expected physical discomforts
- ✓ Unexpected or unforeseeable risks/discomforts
- ✓ Inconveniences to the subject

XI. ALTERNATIVES:

State alternative procedures and/or treatments that may be available.

XII. PAYMENTS AND COSTS:

A statement regarding the cost of the protocol to the patient, including any costs that might not be expected to be covered by the patient's insurance plan, need to be detailed. Any coverage for these costs not covered by the patient's insurance plan should be explained.

Sample language

All funding provided by [insert sponsor name] to conduct this study here is paid to the Lancaster General Hospital for the staff's work to collect the study data and manage the study. [insert if there is a non-LGH collaborating practice] Lancaster General Hospital then pays [practice] to collect the study data from those subjects seen by [investigator].

If you choose to take part in this study, will it cost you anything?
[Study sponsor] will pay for all [tests, procedures, devices] that are done only because you are part of the study. This includes… You and your insurance company are responsible for the costs of all [tests, procedures, devices] that you would otherwise have for treatment of your [insert disease], even if you weren't in the study. However, there is no guarantee that your insurance company will cover 100% of these costs. You should check with your insurance company to verify coverage or payment of these costs.

[insert if subjects are paid, reimbursed for mileage, etc]

Will you be paid for taking part in this study?
For the [list visits] visits, you will receive $XX.00. [Alternatively, or in addition, insert details of mileage reimbursement if applicable.] We will pay you using a pay card system. To get the pay card

set up, we will need you to complete a W-9 form with your social security number. (The W-9 will be kept in a secure manner by our Accounting Office.) Then, we will give you the pay card and keep track of the money that you are due. Weekly after each visit, we will put the amount of money that you are due into the card account. You can use the card like you would a debit card or gift card at many locations.

It is important that you do not lose the pay card. Cost for replacing lost or stolen card will be your responsibility. The cost to replace the debit card is $5.00 and that amount will be deducted from your study visit payment. If you do not complete the study, you will still be paid for the visits you have completed.

PLEASE NOTE: LG Health is required to report to the IRS any cumulative payments for participation in research that exceeds a total of $600 in a calendar year.

XIII. COMPENSATION FOR INJURY OR COMPLICATION:

Any statement regarding any possible compensation plan that the sponsor has should be included here.

Example paragraph regarding sponsor compensation for injury related to research:
What if you are injured because of the study?

If you are injured because of taking part in this study, you could need medical treatment for your injuries. The sponsor has a program that may pay for medical costs of injuries that are a direct result of participation in the study. The program does not pay for lost wages, lost time or discomfort for such injuries

OR

If you are injured because of taking part in this study, you could need medical treatment for your injuries. You or your insurance company would be responsible for the costs of that treatment.

Include verbatim:

Lancaster General Hospital does not have a program to pay for medical expenses, lost wages, lost time or discomfort for such injuries.
You do not waive any legal rights to seek compensation by signing this consent form.

XIV. PREGNANCY / BREASTFEEDING WAIVER:

If female subjects of reproductive age are included in the study, a separate statement of risk to the fetus or breast-fed child is required along with a statement that if pregnant or nursing, study participation is excluded. If maternal risk is expected, a commitment to avoid pregnancy by standard effective means and acceptance of a pregnancy test prior to enrollment in the study must be obtained.

The following statement should be included in cases where maternal risk is expected:

If you are a woman of child-bearing age, we will do a pregnancy test before you can start the study. You will need to use an effective method of birth control while you are in the study. If you are nursing a baby, you cannot take part in the study.

XV. QUESTIONS / FURTHER INFORMATION:

Include verbatim:

If you have any questions about this research or if you believe you have been injured as a result of participating in this research study, you can contact Dr. [principal investigator's or collaborator's full name] at [phone number]. (See Section III for complete list of investigators and collaborators.)

XVI. SUBJECT'S RIGHTS OR QUESTIONS:

Include verbatim:

The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at Lancaster General Health. If you have any questions about your rights as a research participant, or if you have complaints or concerns, you may send an e-mail to the HRPP (SM-HRPP@lghealth.org). You also may call the Chair of the Institutional Review Board at Lancaster General Hospital at 717-544-5091.

XVII. VOLUNTARY PARTICIPATION:

Include verbatim:

Your participation in this study is voluntary. This means it is your choice whether or not to take part. You may refuse to take part in this study, or you may withdraw from this study at any time. You will not lose benefits you would otherwise receive or suffer any penalty if you do so. You also will not jeopardize the medical care you receive from your doctor. If we learn of important new information during the study that may affect your decision to participate, we will provide this information as soon as possible to you and your doctor. You then can review and discuss it together.

XVIII. TERMINATION OF PARTICIPATION / RIGHT TO WITHDRAWAL:

Describe in lay person's terms the procedure for the orderly termination of participation by the subject in the research study.

XIX. CONFIDENTIALITY:

Describe the extent to which records identifying the patient will be maintained and who will have access to these records. The FDA or OPRR may review original research records, so a statement of this possibility is appropriate.

If this research represents a clinical trial that must be registered on www.Clinicaltrials.gov, you must include the following statement: A description of this clinical trial will be available on http://www.Clinicaltrials/gov as required by federal law 42 CFR Part 11. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

XX. STATEMENT OF CONSENT:

The following statements must be included verbatim:

I have read the above information, or have had it read to me. I understand the purpose of the study and the possible benefits and risks of taking part in it. I have had the chance to ask questions, and all of my questions have been answered to my satisfaction. I freely give my informed consent to take part in this study.

XXI. HIPAA AUTHORIZATION

To conduct clinical research studies, we need to use and disclose patients' health information in several ways. The Federal law known as the Health Insurance Portability and Accountability Act ("HIPAA") requires that we get you to authorize the ways we use and disclose your health information.

A. A description of the health information to be used or disclosed that identifies the information in a specific and meaningful fashion. You must list in the authorization all the information you plan to use or disclose. This includes standard PHI, as well as subjects' history, physical findings, and laboratory test results.
The Researchers may also use and disclose billing information from visits, tests, procedures and/or hospital stays, if required for the study. We will remove your name and other identifiers from your billing records before we use or disclose them.

B. Please provide the specific identity of the person(s), or class or persons, authorized to make the requested use or disclosure of the health information. In most cases, this will be the principal investigator(s) and his or her research team.

C. Please disclose the specific individuals and/or organizations who will receive the subjects' health information, such as the clinical research organization and central laboratories, as well as oversight agencies such as the Institutional Review Board or the FDA, or, where applicable, the Federal Office for Human Research Protections (OHRP).

D. Please provide a description of each purpose of the requested use or disclosure such as a description of the study that you may already be using on the consent form.

E. Please provide the expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study", "none", or similar language is sufficient.

F. Please state that the subject has the right to refuse to sign the authorization. This statement is the same as the one current research regulations require.

G. Please provide that the subject has the right to revoke their authorization in writing to prevent the subsequent use or disclosure of their protected health information. An example of this language is as follows:

> You may withdraw from the study at any time. If you withdraw, we will ask you to come back one more time for a last exam and to return your unused medicines. You must withdraw in writing in order to withdraw your permission for us to continue to use the data that we have already collected about you. Even if you withdraw our permission to use the data

about you, we are required by the FDA to record anything that relates to the safety of these drugs.
Suggestive verbiage that can be utilized "you may see how your information will be utilized as described in LG Health Privacy Practice, which is located on the LGHealth.org website under "Patient & Visitors."

H. Please request the signature of the individual and date. If the authorization is signed by a personal representative of the subject, a description of such representatives' authority to act for the individual/subject must also be provided.

The consent form must be dated and each page must be numbered. (see footer)

Spelling and grammar must be correct.

XXII. SIGNATURE LINES:

_____	_____	_____
Patient Name (Printed)	Signature	Date
_____	_____	_____
Name of legally authorized representative if applicable (Printed)	Signature of legally authorized representative	Date
_____	_____	_____
Name of person obtaining consent (printed)	Signature of person obtaining consent	Date

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