Informed Consent Form to be in a Research Study

STUDY TITLE:	Medtronic Imaging Study of Lead Implant for His Bundle Pacing ("IMAGE-HBP Study")
SPONSOR:	Medtronic, Inc. 8200 Coral Sea Street NE Mounds View, MN 55112
PRINCIPAL INVESTIGATOR:	[PI Name] [Address] [City, State, Zip Code]
STUDY RELATED TELEPHONE:	During regular office hours: [Phone #] Outside regular office hours: [Phone #]

Why am I being asked to be in this study?
You are being asked to be in a study that involves research with human subjects. Being in this study is voluntary. Before you decide if you would like to be in the study, it is important you understand why the study is being done and what it will involve. Please read this form carefully and ask your doctor any questions you may have. After reading this form and asking any questions you have, if you decide to be in this study you will sign and date the last page of this form.

You are being asked to be in this study because your doctor recommends that you get a pacemaker and believes that His bundle pacing may be appropriate to treat your abnormal heartbeat. A pacemaker is a small battery-powered device that sends electrical pulses to help the heart beat more regularly. The electrical pulses are sent to the heart by insulated wires called leads. If you agree to be in this study you will get a lead called the Medtronic SelectSecure™ MRI SureScan™ Model 3830 lead for His bundle pacing ("study lead") as part of your pacemaker system.

The study lead mentioned above is approved by the U.S. Food and Drug Administration (FDA) for use in patients who receive an implanted pacemaker system.

When a pacemaker system sends the electrical pulses to the heart, the process is called pacing. This study will be looking at a type of pacing called His bundle pacing. In His bundle pacing, the electrical pulses are sent to part of the heart that is sometimes called the "Bundle of His". His bundle pacing is not considered experimental and it can be done outside of a research study.

However, His bundle pacing is not as commonly used as right ventricular pacing where the pacing is done in a different part of the heart. Researchers want to learn more about the implant procedure for His bundle pacing because the location of pacing may impact how similar the pacemaker therapy is to a natural heartbeat. The data collected in this study may be used in the future to help researchers learn how to improve the process of implanting leads for His bundle pacing.

Study purpose:
The purpose of this study is to assess the implant success rate of the study lead for His bundle pacing and collect additional information to help improve the tools and implant workflow for His bundle pacing.

How long will I be in the study? How many people will be in the study?
Up to 70 subjects will be in this study in the United States. Your participation in the study may last about 1 year. The overall study is expected to last a total of 2 years and 4 months.

What are my responsibilities during the study?

Being in this study, it is important that you:

- Tell the study doctor about your medical and medication history;
- Attend all visits scheduled with the study doctor;
- Call the study doctor's office to reschedule a missed visit as soon as possible;
- Report any injuries, hospitalizations, emergency room visits, symptoms or complaints to the study doctor or study nurse as soon as possible.

What will happen if I am in this study?

Study Procedures:

If you decide to be in this study, the study doctor and study nurse will collect information about you and your medical history. This could include medications you currently take and any other information in your medical records related to your condition or treatment that may be relevant to your being in the study.

None of the procedures in this study are experimental.

Enrollment/Baseline Visit

At this visit, the following will be collected:

- Basic information about you such as age, ethnicity, etc.
- Medical history

Implant Visit

At this visit, the pacemaker system will be implanted and the following will be done:

- Records about the procedure will be collected.
- Electrical measurements will be recorded during the implant and attachment of the study lead.
- An Electrophysiology recording system (computer recording system) will be temporarily connected to the study lead with cables (cords). The EP recording system will record the electrical signals coming from the study lead.
- Fluoroscopy Cine images will be collected which are like short movies of the motion in your heart.
- An ECG recording will be performed.
- Device data from your pacemaker will be downloaded and saved.

Some of the procedures, including electrical measurements and fluoroscopy cine imaging are study procedures that are not normally required in a routine implant procedure. These activities are expected to add approximately 20 minutes to the procedure time.

The study doctor will evaluate the rhythm of your heart's pacing and classify it as one of two types. When the electrical measurements are collected, a few additional measurements will be collected from subjects with one of the pacing types. Collecting the additional measurements may add up to 10 minutes to this visit.

Discharge Visit (Before you leave the hospital)

At this visit the following procedures will be done:

- Electrical measurements will be recorded.
- An ECG recording will be performed.
- Device data from your pacemaker will be downloaded and saved.
- A Cardiac CT scan will be done while you are still in the hospital or up to 17 days after your implant procedure.
- The study doctor will assess for any unwanted effects.

Follow-up Visits (1 week, 3 months, 6 months, and 12 months after implant)
At this visit the following procedures will be done:

- Electrical measurements will be recorded.
- An ECG recording will be performed
- Device data from your pacemaker will be downloaded and saved.
- The study doctor will assess for any unwanted effects.

At the 1 week and 3 month visits, you will also wear a Holter monitor. The Holter monitor is portable device that records electrical signals from your heart. You will only wear the monitor during the visit and you will take it off before you leave. If you do not wear the Holter monitor at your 3 month visit, you will wear it at the 6 month visit instead.

At the 3 month visit only, the study doctor will evaluate the rhythm of your heart's pacing and classify it as one of two types. When the electrical measurements are collected, a few additional measurements will be collected from subjects with one of the pacing types. Collecting the additional measurements may add up to 10 minutes to this visit.

System Modification
If you have a procedure to replace, remove, or modify your implanted system, for any reason, information about the procedure will be collected for the study.

What are the possible risks, side-effects, discomforts and inconveniences?
All devices being used in this study are approved. You will receive a separate surgical consent form from your study doctor explaining the implant procedure and the risks of having the pacemaker system implanted. The risks of the implant procedure are the same as the risks for any patient who receives the same procedure outside of this study.

Risks from participating in this study may include the following:

Risk associated with Fluoroscopy exposure:

- During the implant procedure, additional cine recordings will be collected. The duration of the extra radiation exposure is expected to be less than 5 minutes of time beyond what would be experienced during a standard implant procedure.

Risk associated with Cardiac CT Scans:

- Exposure to radiation from one test is similar to the amount of radiation you are naturally exposed to over one to five years.
- The CT scan may detect an incidental finding, which is something that doesn't cause symptoms now but may require more tests after being found.
- Allergic reaction to contrast used during the Cardiac CT Scan

If you are or you become pregnant, there may be risks to you or your unborn child that are not yet known. If you become pregnant during the study, you should tell the study doctor as soon as possible.

There may be additional risks related to this study that are not yet known.

What are the possible benefits of the study?
If you agree to be in this study, it is possible that you may not have any direct medical benefits. The information from this study may benefit other patients who receive pacemakers in the future.

What happens when I end being in the study?
Your participation in the study is expected to end after the 12-month follow-up visit. You will continue to receive routine care from your doctor when your participation in the study ends.

What other treatment choices do I have if I am not in the study?
You do not have to be in this study to receive a pacemaker system. His bundle pacing can also be done outside of this study. If you decide not to be in this study, there is other care available to you. For example, you may receive a different commercially available device or lead, right ventricular pacing instead of His bundle pacing, another surgical procedure, or treatment with drugs.

You may choose no treatment at all. You should discuss other treatments and their possible risks and benefits with your doctor.

Who is paying for this study?
The study site will receive payment from Medtronic for work involved in collecting study data and managing the study at the site and for procedures done solely for the study.

Will I be paid for being in this study?
You will not be paid for being in this study.

What will I have to pay for if I am in this study?
Testing and services done only for the study will be provided at no cost to you. These costs will not be billed to your health insurer or Medicare.

You or your health insurer or Medicare will be responsible for all costs that are part of your normal medical care. If your health insurer or Medicare requires a co-payment, co-insurance, or deductible, you will be responsible for making that payment.

What happens if I am injured or hurt during this study?
The study doctor, the hospital, and the study sponsor will not routinely pay for any medical care or provide any other payment to you if you are injured or become ill because of the study. However, any immediate medical treatment you need will be provided.

By agreeing to this, you do not give up any of your legal rights. You do not release the study sponsor, study doctor, or the hospital from responsibility for their negligence.

Your Medtronic pacemaker comes with a warranty. If the pacemaker does not work the way it should, the warranty will apply.

Do I have the right to refuse to be in this study or to leave this study?
Being in this study is voluntary. You may choose not to be in the study or to leave the study at any time for any reason. If you choose not to be in the study or to leave the study, this will not result in any penalty and you will not lose any benefits to which you are entitled. Your regular care and your relationship with the hospital or clinic and your doctors will not be affected.

You will be told about any new information that may make you change your mind about staying in the study. You may be asked to sign a new consent form if this occurs.

You may leave the study simply by telling the study doctor. There are no specific tests that are required prior to leaving the study. You may be asked to come in for a final device check or visit. All of your health information collected for the study cannot be removed from the study data and will be used as described in this form.

The study doctor may take you out of the study without your permission if:

- It is in your best medical interest.
- You do not follow your study doctor's instructions.
- The study sponsor or FDA stops the study.

If this happens you will be told and the reasons will be explained to you.

What is the role of the sponsor's representative?

Trained Medtronic personnel may be present at the implant and at study follow-up visits. The role of the Medtronic person is to give technical support. The Medtronic person may use a programmer to interact with your device system used in this study. All of these actions will be done under the careful direction of your study doctor.

What happens if you pass away while in the study?

If you pass away while you are in the study, the study doctor will ask your family or other authorized representative for permission to retrieve medical records surrounding your death and to remove the pacemaker system. If the study doctor has this permission, the pacemaker and lead(s) will be removed and sent back to the sponsor. The sponsor will collect information from the pacemaker system. Your family or other authorized representative does not have to grant permission.

The study does not mandate that an autopsy be performed. If an autopsy is performed, a copy of the autopsy report and a copy of the death certificate, if available, will be sent to the sponsor as part of the information collected for the study.

How will the sponsor use the study information?

If you decide to participate in the study, Medtronic (including, for purposes of this section, its agents and contractors) and others who work with the study will see health information about you. This consent form and another document called an Authorization to Use and Disclose Health Information ("Authorization") govern how your health information is disclosed and used.

The Authorization describes how your health information may be used and/or disclosed by your doctor (the study investigator), the hospital or clinic, and their respective staffs. You agree to allow access to and use of your health information in accordance with the Authorization, as well as disclosure to Medtronic.

This consent form describes the study, and what Medtronic will do with the study data, including your health information received during the study. Medtronic will keep your health information confidential in accordance with all applicable laws and regulations. Medtronic may use your health information to conduct this research, as well as for additional purposes, such as overseeing and improving the performance of its device, new medical research and proposals for developing new medical products or procedures, and other business purposes. Any reports or publications about the study or any other research will not include your name or a description of you. Information received during the study will not be used to market to you; your name will not be placed on any mailing lists or sold to anyone for marketing purposes. U.S. Food and Drug Administration (FDA) regulations, as well as other applicable laws, control Medtronic's work in developing and assuring the safety and quality performance of its medical devices. Medtronic may disclose your health information to the FDA, as well as to other U.S. and foreign government authorities responsible for assuring the safety of medical devices. Medtronic also may disclose your health information to institutional review boards and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. You agree to allow Medtronic to use study data in these ways. You also agree to allow FDA and other governmental authorities to inspect your health information.

To participate in the study, you will need to sign this consent form and the Authorization to Use and Disclose Health Information.

Where can I find out about the study results?
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 can I call with questions, complaints or if I'm concerned about my rights as a participant?
If you have any questions about the research or being in this study, you should contact [insert name] at [insert telephone number].

If you think you have a research-related injury, you should contact [insert name] at [insert telephone number].

If you have any questions about your rights as a research subject you should contact [insert name] at [insert telephone number].

What Does My Signature on this Consent Form Mean?
Your signature on this form means that:

- You have read the information given to you in this form
- You accept the conditions of this form
- You agree to join the study

You will not give up any legal rights by signing this consent form. You will receive a copy of this consent form

Statement of the Subject:
I have read this consent form and the research study has been explained to me. My questions have been answered to my satisfaction. I understand that by signing this form, I have not waived my legal rights nor released anyone from negligence. I choose to volunteer for the study. I have been given a copy of this form.

Printed Name of Subject

Signature of Subject or Subject's Legally Authorized Representative, if applicable — Date

Printed Name of Legally Authorized Representative, if applicable

Signature of Person Obtaining Consent — Date

Printed Name of Person Obtaining Consent