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Signed By	Meaning of Signature	Date/Time (UTC)
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Berg, Melinda, RN	Document Approver	05/11/2018 16:29:50

Informed Consent Form to be in a Research Study

STUDY TITLE:	**Medtronic REVAMP Study** (**RE**modeling the Left **V**entricle with **A**trial **M**odulated **P**acing)
SPONSOR:	Medtronic, Inc. ("Medtronic") Cardiac Rhythm and Heart Failure Clinical Research 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 you have been diagnosed as having heart failure with preserved ejection fraction ("HFpEF"), and are currently using a market-released Medtronic dual chamber pacemaker device with a Sleep Function ("pacemaker").

Study purpose:
The purpose of this study is to see if pacing the right atrium of the heart at a higher rate for periods of time can help the left ventricle (LV) pump blood better, and if it improves exercise capacity and quality of life for patients who have HFpEF, normal to small LV chambers, and evidence of thickened walls.

System description:
This study will be conducted with patients who have a market-released Medtronic dual chamber pacemaker with a Sleep Function, and have had this pacemaker for at least 6 months. Any Medtronic dual chamber pacemaker with the Sleep Function will qualify.

How long will I be in the study? How many people will be in the study?
Up to 50 subjects may be enrolled (consented) to ensure 30 subjects receive pacing therapy in this study, which will take place at up to 10 sites in the United States. Your participation in the study will last about 3 months. The overall study is expected to last a total of 24 months.

What are my responsibilities during the study?
Being in this study, it is important that you:

- Tell the study doctor or study nurse about your medical and medication history;
- Attend all in-office visits and phone visits scheduled with the study doctor or study nurse;
- 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 and are eligible, the study doctor and study nurse will collect information about you and your medical history. This includes any medication 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.

For this study, your study doctor or study nurse will schedule 4 in-office visits and 5 phone visits with you. The study doctor or study nurse will call you for 5 telephone visits. You must make sure that you can attend each visit as scheduled.

The order of your study visits and phone calls will be as follows:

- Enrollment
- Baseline Visit (in-office)
- Phone Call with Study doctor or nurse 24 hours after your Baseline Visit
- Phone Call with Study doctor or nurse 5 days after your Baseline Visit
- Phone Call with Study doctor or nurse 2 weeks after your Baseline Visit
- Office Visit 4 weeks after your Baseline Visit
- Phone Call with Study doctor or nurse 6 weeks after your Baseline Visit
- Office Visit 8 weeks after your Baseline Visit
- Phone Call with Study doctor or nurse 10 weeks after your Baseline Visit
- Office Visit 12 weeks after your Baseline Visit/Study Exit

Office Visit 1: Baseline Visit

This visit will occur within 30 days after you have enrolled in this study. You are considered enrolled after you sign this consent form. You must sign this consent form before any of the study tests or programming may be done.

In this study, your heart will be paced at a higher rate than your doctor would usually prescribe. Your pacemaker will be programmed to pace at 100 beats per minute ("bpm") for 5 hours while you sleep at night. This procedure is experimental.

The following procedures will be completed, and information will be collected:

- Study staff will ask general information about you, such as your date of birth, gender, and ethnicity;
- Study staff will review your medical history, medication use, and confirm you are eligible to participate in the study;
- If you are able to become pregnant, a small amount of blood (approximately 2 to 3 teaspoons) or urine may be collected to check for pregnancy;
- Physical exam including height, weight, heart rate, symptoms, blood pressure and an assessment of your heart failure;
- Complete 2 quality of life questionnaires;
- Perform a 6-Minute Walk Test;
- An Echocardiogram will be done with a probe placed on the outside of your chest. This test uses ultrasound, or sound waves, to make a picture of your heart. An echocardiogram is painless and does not involve radiation;
- Blood draw to collect approximately 4 tubes of blood (about 5 teaspoons total)

- Study staff will download information from your pacemaker and program your pacemaker so that it paces your heart at 100 bpm. This will let you know how it feels to have your pacemaker programmed at 100 bpm while you are in the office for this visit. You will stay for at least 30 minutes of observation to make sure that you can tolerate this level of pacing. If you cannot tolerate the 100 bpm programming, please let your study doctor or study nurse know and you will be exited from the study;
- Study staff will download information from your pacemaker again.
- Study staff will provide you with a finger pulse oximeter monitor to use at home during the study, and will explain how it will be used;
- Your pacemaker will stay at 100 bpm when you leave this visit. Your pacemaker will return to its usual pace at 5:00 AM the next day. Each night, it will return to 100 bpm for 5 hours while you sleep.

Scheduled Follow-Up Phone Calls
The study doctor or study nurse will call you at home at regular intervals to ask how you are feeling: 24 hours after your Baseline visit, 5 days after your Baseline visit, 2 weeks after your Baseline visit, 6 weeks after your Baseline visit, and 10 weeks after your Baseline visit. The study doctor or study nurse will ask you a standard set of questions about your symptoms, current medications, and overall health. You will also be asked to measure your heart rate, which you can do using the finger pulse oximeter monitor the study doctor or study nurse gave to you to take home during the Baseline visit.

Office Visit 2: 4 Week Follow-Up
During this visit, you will be assigned (randomized) to one of two study groups. Being randomized means a computer will put you into a group by chance. It is like drawing straws:

- Treatment Group– Pacemaker will continue to be programmed at 100 bpm for 5 hours each night.
- Control Group – Pacemaker will be programmed to the return to the standard settings in place before you began this study.

You will have a two in three chance (2/3) of being put in the Treatment Group, and one in three (1/3) chance of being put in the Control Group. You will not be told which group you are in, but your study doctor and study nurse will know.

The following procedures will be done, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure, and an assessment of your heart failure;
- Complete a quality of life questionnaire;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately 5 teaspoons total);
- Your study doctor or study nurse will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- You will be randomized (assigned to one of the two study groups as described above);
- Study staff will program your pacemaker according to the group you are assigned to;
- Study staff will download information from your pacemaker again.

Office Visit 3: 8 Week Follow-Up
The following procedures will be completed, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure and an assessment of your heart failure;
- Complete 2 quality of life questionnaires;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately 5 teaspoons total);
- Study staff will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- Study staff will program the pacemaker according to what your study doctor thinks will be best for you;
- Study staff will download information from your pacemaker again.

Office Visit 4: 12 Week Follow-Up and/or Study Exit
The following procedures will be done, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure and an assessment of your heart failure;
- Complete a quality of life questionnaire;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately 5 teaspoons total);
- Your study doctor or study nurse will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- Study staff will program your pacemaker according to what your study doctor thinks will be best for you;
- Study staff will download information from your pacemaker again;
- You will return the finger pulse oximeter monitor that you have been using at home at this visit.

At the end of this visit, you will be exited from the study.

Unscheduled Visit
If you visit your study doctor about your heart symptoms and this is not a scheduled study visit, the following will happen:

- Study staff will ask if you have had any problems or symptoms since your last visit;
- Study staff may review your medication use;
- Study staff may do a physical exam including height, weight, heart rate, symptoms, blood pressure;
- Study staff may perform an echocardiogram;
- Study staff may do a blood draw and collect approximately 4 tubes of blood (approximately 5 teaspoons total);
- Study staff may perform an initial pacemaker interrogation, program the pacemaker, perform a second pacemaker interrogation, and then will save the results.;
- If you seek treatment from a physician or nurse other than your REVAMP study doctor or study nurse, please provide your REVAMP study ID card to the physician or nurse treating you at this visit.

Blood Samples: Approximately 4 blood tubes (about 5 teaspoons total) will be collected during the four in office visits of the study. If you agree below, the blood tubes **will be analyzed and stored at a**

separate certified laboratory to be used as part of this study or used as part of future studies. The labels on the tubes will not include your name or any personal information.

- One or two tubes will be used to measure your baseline heart health to ensure that the pacing therapy given in this study is not causing too much stress on your heart. Following this analysis any remaining blood samples will be stored at the laboratory.
- Two tubes will be stored and may be analyzed later if this study shows benefit to the subjects. Additional analysis of blood markers for stiffness of your heart muscle will help researchers understand how the therapy is working.

The stored blood sample may be used in the development of tests, products, or discoveries that may have potential commercial value. As a study subject, you will not be paid or receive money. By signing this consent form, you agree not to seek a share of any profits that might result. Medtronic may do more tests on the blood samples in the future. However, since the purpose of the tests is to discover new blood markers of risk which may need to be validated in additional studies, we will not inform you of the results.

The tubes that may be used for blood markers will be **uniquely coded and stored separately (in a different location) from the "key" which identifies the samples. Only the key will have the identifying information that links the sample to you.**

You can choose not to provide a blood draw for the collection of the two blood samples testing for blood markers. If you decide not to allow collection of two additional tubes in your blood draw, you may still participate in this study. Please put a checkmark in the box(es) to indicate whether or not you are willing to allow us to collect and use your blood as described here.

1. I wish to provide the blood sample tubes that will be used to assess my current baseline heart health (required for participation in this study).

   Yes ☐

   No ☐

2. I permit Medtronic to use my stored blood tubes for other blood marker research for the purposes and duration of this study.

   Yes ☐

   No ☐

What are the possible risks, side-effects, discomforts and inconveniences?

All the risks of having your implanted pacemaker, and having your heart paced, are the same whether you are in the study or not. There may be additional risks associated with increased pacing by changing the Sleep Function setting, as described in this consent form, that include:

- increased risk of heart failure;
- atrial arrhythmia;
- chest pain;
- ischemia;
- dizziness;

- palpitations;
- heart racing;
- shortness of breath;
- difficulty sleeping.

Your pacemaker may be set at 100 bpm, an increased pacing rate, longer than expected if several of the pacemaker features are changed at the same time.

If you do not come in for your scheduled exit visit, your device will continue to have the 100 bpm pacing rate and your pacemaker battery may not last as long as it would if it were reset to its settings from before the study. This could mean that you might need surgery to remove or replace the pacemaker 1 to 2 years earlier than if the pacing setting was returned to the pre-study rate.

- Surgery associated with removing your current pacemaker and inserting a new pacemaker could lead to:
  - infection;
  - blood clot;
  - having an unattached particle travel through the bloodstream and lodge in a vessel;
  - buildup of blood under the skin;
  - stroke;
  - collapsed lung;
  - collection of blood in the space between the chest wall and the lung;
  - nerve damage.

The study also requires a blood draw. The risks of a blood draw in this study are the same as those associated with a routine blood draw in an office visit and include:

- pain;
- a bruise at the point where the blood is taken;
- redness and swelling of the vein;
- infection;
- fainting.

The Echocardiogram has no known serious side-effects. The ultrasound probe may be uncomfortable when it is applied to the chest. The ultrasound gel may cause skin irritation.

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, tell your study doctor right away. There may be additional risks related to this study that are not yet known.

What are the possible benefits of the study?
The potential benefits of having your pacemaker programmed to 100 bpm include:

- Improvement in exercise capacity
- Improvement in symptoms

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 with heart failure in the future.

What happens when I end being in the study?
After your final office visit, your study doctor or study nurse will determine how to program the pacing in your pacemaker. No further study data will be collected or study visits will occur. At the completion of this study, you will continue to receive standard medical care.

What other treatment choices do I have if I am not in the study?
You do not have to be in this study to be treated for heart failure with preserved ejection fraction (HFpEF). You are currently receiving treatment for your heart failure according to medical care standards, and that will continue whether or not you choose to participate in this study.

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 be paid $25 per scheduled in-office visit to reimburse you for transportation and other costs that you may incur by participating in this study as well as for time you spend completing questionnaires and other study-related documents. You will receive payment after you complete the Baseline, 4 week, 8 week, and 12 week in-office study visits. The study doctor or study nurse will tell you how you will be paid.

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.

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

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.

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. If you choose to leave the study after Office Visit 2, and you are in the Treatment Group, to ensure your safety you will be asked to come in for a final pacemaker check and office visit. The same procedures and tests will be performed as would have happened during the Office Visit 4: 12 Week Follow-Up Visit/Study Exit. All of your health information collected for the study cannot be removed from the study data, and will be used as described in this consent form.

If you cannot tolerate the 100 bpm programming, please let your study doctor or study nurse know and you will be exited from the study.

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 or study nurse's instructions;
- You are unable to attend all in-office visits and phone visits scheduled with the study doctor or study nurse;
- The study sponsor, Institutional Review Board, or regulatory authority stops the study for any reason.

If this happens, you will be told and the reasons will be explained to you. Following exit from the study, you will continue to receive standard medical care.

What is the role of the sponsor's representative?

Trained Medtronic personnel may be present at the in-office study visits. The role of Medtronic personnel is to give technical support. The Medtronic personnel may use a programmer to interact with your pacemaker 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. If the study doctor has this permission, the pacemaker will be explanted and sent back to the sponsor. The sponsor will collect information from the pacemaker. 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 the 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 consent 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 Date

Statement of the Principal Investigator or authorized designee for conducting the informed consent process:

I have reviewed and discussed this Informed Consent Form with the subject.

_____
Printed name of principal investigator or authorized designee for conducting the informed consent process

_____ _____
Signature of principal investigator or authorized designee Date

Informed Consent Form to be in a Research Study

STUDY TITLE:	**Medtronic REVAMP Study** (**RE**modeling the Left **V**entricle with **A**trial **M**odulated **P**acing)
SPONSOR:	Medtronic, Inc. ("Medtronic") Cardiac Rhythm and Heart Failure Clinical Research 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 you have been diagnosed as having heart failure with preserved ejection fraction ("HFpEF"), and are currently using a market-released Medtronic dual chamber pacemaker device with a Sleep Function ("pacemaker").

Study purpose:
The purpose of this study is to see if pacing the right atrium of the heart at a higher rate for periods of time can help the left ventricle (LV) pump blood better, and if it improves exercise capacity and quality of life for patients who have HFpEF, normal to small LV chambers, and evidence of thickened walls.

System description:
This study will be conducted with patients who have a market-released Medtronic dual chamber pacemaker with a Sleep Function, and have had this pacemaker for at least 6 months. Any Medtronic dual chamber pacemaker with the Sleep Function will qualify.

How long will I be in the study? How many people will be in the study?
Up to ~~40~~50 subjects may be enrolled (consented) to ensure 30 subjects receive pacing therapy in this study, which will take place at up to ~~5~~10 sites in the United States. Your participation in the study will last about 3 months. The overall study is expected to last a total of ~~12~~24 months.

What are my responsibilities during the study?
Being in this study, it is important that you:

- Tell the study doctor or study nurse about your medical and medication history;
- Attend all in-office visits and phone visits scheduled with the study doctor or study nurse;
- 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 and are eligible, the study doctor and study nurse will collect information about you and your medical history. This includes any medication 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.

For this study, your study doctor or study nurse will schedule 4 in-office visits and 5 phone visits with you. The study doctor or study nurse will call you for 5 telephone visits. You must make sure that you can attend each visit as scheduled.

The order of your study visits and phone calls will be as follows:

- Enrollment
- Baseline Visit (in-office)
- Phone Call with Study doctor or nurse 24 hours after your Baseline Visit
- Phone Call with Study doctor or nurse 5 days after your Baseline Visit
- Phone Call with Study doctor or nurse 2 weeks after your Baseline Visit
- Office Visit 4 weeks after your Baseline Visit
- Phone Call with Study doctor or nurse 6 weeks after your Baseline Visit
- Office Visit 8 weeks after your Baseline Visit
- Phone Call with Study doctor or nurse 10 weeks after your Baseline Visit
- Office Visit 12 weeks after your Baseline Visit/Study Exit

Office Visit 1: Baseline Visit

This visit will occur within 30 days after you have enrolled in this study. You are considered enrolled after you sign this consent form. You must sign this consent form before any of the study tests or programming may be done.

In this study, your heart will be paced at a higher rate than your doctor would usually prescribe. Your pacemaker will be programmed to pace at 100 beats per minute ("bpm") for 5 hours while you sleep at night. This procedure is experimental.

The following procedures will be completed, and information will be collected:

- Study staff will ask general information about you, such as your date of birth, gender, and ethnicity;
- Study staff will review your medical history, medication use, and confirm you are eligible to participate in the study;
- If you are able to become pregnant, a small amount of blood (approximately 2 to 3 ~~tablespoons~~teaspoons) or urine may be collected to check for pregnancy;
- Physical exam including height, weight, heart rate, symptoms, blood pressure and an assessment of your heart failure;
- Complete 2 quality of life questionnaires;
- Perform a 6-Minute Walk Test;
- An Echocardiogram will be done with a probe placed on the outside of your chest. This test uses ultrasound, or sound waves, to make a picture of your heart. An echocardiogram is painless and does not involve radiation;
- Blood draw to collect approximately 4 tubes of blood (about 5 teaspoons total)

- Study staff will download information from your pacemaker and program your pacemaker so that it paces your heart at 100 bpm. This will let you know how it feels to have your pacemaker programmed at 100 bpm while you are in the office for this visit. You will stay for at least 30 minutes of observation to make sure that you can tolerate this level of pacing. If you cannot tolerate the 100 bpm programming, please let your study doctor or study nurse know and you will be exited from the study;
- Study staff will download information from your pacemaker again.
- Study staff will provide you with a finger pulse oximeter monitor to use at home during the study, and will explain how it will be used;
- Your pacemaker will stay at 100 bpm when you leave this visit. Your pacemaker will return to its usual pace at 5:00 AM the next day. Each night, it will return to 100 bpm for 5 hours while you sleep.

Scheduled Follow-Up Phone Calls
The study doctor or study nurse will call you at home at regular intervals to ask how you are feeling: 24 hours after your Baseline visit, 5 days after your Baseline visit, 2 weeks after your Baseline visit, 6 weeks after your Baseline visit, and 10 weeks after your Baseline visit. The study doctor or study nurse will ask you a standard set of questions about your symptoms, current medications, and overall health. You will also be asked to measure your heart rate, which you can do using the finger pulse oximeter monitor the study doctor or study nurse gave to you to take home during the Baseline visit.

Office Visit 2: 4 Week Follow-Up
During this visit, you will be assigned (randomized) to one of two study groups. Being randomized means a computer will put you into a group by chance. It is like drawing straws:

- Treatment Group– Pacemaker will continue to be programmed at 100 bpm for 5 hours each night.
- Control Group – Pacemaker will be programmed to the return to the standard settings in place before you began this study.

You will have a two in three chance (2/3) of being put in the Treatment Group, and one in three (1/3) chance of being put in the Control Group. You will not be told which group you are in, but your study doctor and study nurse will know.

The following procedures will be done, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure, and an assessment of your heart failure;
- Complete a quality of life questionnaire;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately 5 teaspoons total);
- Your study doctor or study nurse will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- You will be randomized (assigned to one of the two study groups as described above);
- Study staff will program your pacemaker according to the group you are assigned to;
- Study staff will download information from your pacemaker again.

Office Visit 3: 8 Week Follow-Up
The following procedures will be completed, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure and an assessment of your heart failure;
- Complete 2 quality of life questionnaires;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately ~~5 tablespoons each~~5teaspoons total);
- Study staff will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- Study staff will program the pacemaker according to what your study doctor thinks will be best for you;
- Study staff will download information from your pacemaker again.

Office Visit 4: 12 Week Follow-Up and/or Study Exit
The following procedures will be done, and information will be collected:

- Study staff will review your medication use;
- Physical exam including height, weight, symptoms, heart rate, blood pressure and an assessment of your heart failure;
- Complete a quality of life questionnaire;
- Perform a 6-Minute Walk Test;
- Echocardiogram;
- Blood draw to collect approximately 4 tubes of blood (approximately ~~5 tablespoons each~~teaspoons total);
- Your study doctor or study nurse will ask if you have had any problems or symptoms since your last visit;
- Study staff will download information from your pacemaker;
- Study staff will program your pacemaker according to what your study doctor thinks will be best for you;
- Study staff will download information from your pacemaker again;
- You will return the finger pulse oximeter monitor that you have been using at home at this visit.

At the end of this visit, you will be exited from the study.

Unscheduled Visit
If you visit your study doctor about your heart symptoms and this is not a scheduled study visit, the following will happen:

- Study staff will ask if you have had any problems or symptoms since your last visit;
- Study staff may review your medication use;
- Study staff may do a physical exam including height, weight, heart rate, symptoms, blood pressure;
- Study staff may perform an echocardiogram;
- Study staff may do a blood draw and collect approximately 4 tubes of blood (approximately 5 ~~tablespoons each~~teaspoons total);

- Study staff may perform an initial pacemaker interrogation, program the pacemaker, perform a second pacemaker interrogation, and then will save the results.;
- If you seek treatment from a physician or nurse other than your REVAMP study doctor or study nurse, please provide your REVAMP study ID card to the physician or nurse treating you at this visit.

Blood Samples: Approximately 4 blood tubes (about 5 teaspoons total) will be collected during the four in office visits of the study. If you agree below, the blood tubes **will be analyzed and stored at a separate certified laboratory to be used as part of this study or used as part of future studies.** The labels on the tubes will not include your name or any personal information.

- One or two tubes will be used to measure your baseline heart health to ensure that the pacing therapy given in this study is not causing too much stress on your heart. Following this analysis any remaining blood samples will be stored at the laboratory.
- Two tubes will be stored and may be analyzed later if this study shows benefit to the subjects. Additional analysis of blood markers for stiffness of your heart muscle will help researchers understand how the therapy is working.

The stored blood sample may be used in the development of tests, products, or discoveries that may have potential commercial value. As a study subject, you will not be paid or receive money. By signing this consent form, you agree not to seek a share of any profits that might result. Medtronic may do more tests on the blood samples in the future. However, since the purpose of the tests is to discover new blood markers of risk which may need to be validated in additional studies, we will not inform you of the results.

The tubes that may be used for blood markers will be **uniquely coded and stored separately (in a different location) from the "key" which identifies the samples. Only the key will have the identifying information that links the sample to you.**

You can choose not to provide a blood draw for the collection of the two blood samples testing for blood markers. If you decide not to allow collection of two additional tubes in your blood draw, you may still participate in this study. Please put a checkmark in the box(es) to indicate whether or not you are willing to allow us to collect and use your blood as described here.

1. I wish to provide the blood sample tubes that will be used to assess my current baseline heart health (required for participation in this study).

   Yes ☐
   No ☐

2. I permit Medtronic to use my stored blood tubes for other blood marker research for the purposes and duration of this study.

   Yes ☐
   No ☐

What are the possible risks, side-effects, discomforts and inconveniences?

All the risks of having your implanted pacemaker, and having your heart paced, are the same whether you are in the study or not. There may be additional risks associated with increased pacing by changing the Sleep Function setting, as described in this consent form, that include:

- increased risk of heart failure;
- atrial arrhythmia;
- chest pain;
- ischemia;
- dizziness;
- palpitations;
- heart racing;
- shortness of breath;
- difficulty sleeping.

Your pacemaker may be set at 100 bpm, an increased pacing rate, longer than expected if several of the pacemaker features are changed at the same time.

If you do not come in for your scheduled exit visit, your device will continue to have the 100 bpm pacing rate and your pacemaker battery may not last as long as it would if it were reset to its settings from before the study. This could mean that you might need surgery to remove or replace the pacemaker 1 to 2 years earlier than if the pacing setting was returned to the pre-study rate.

- Surgery associated with removing your current pacemaker and inserting a new pacemaker could lead to:
    - infection;
    - blood clot;
    - having an unattached particle travel through the bloodstream and lodge in a vessel;
    - buildup of blood under the skin;
    - stroke;
    - collapsed lung;
    - collection of blood in the space between the chest wall and the lung;
    - nerve damage.

The study also requires a blood draw. The risks of a blood draw in this study are the same as those associated with a routine blood draw in an office visit and include:

- pain;
- a bruise at the point where the blood is taken;
- redness and swelling of the vein;
- infection;
- fainting.

The Echocardiogram has no known serious side-effects. The ultrasound probe may be uncomfortable when it is applied to the chest. The ultrasound gel may cause skin irritation.

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, tell your study doctor right away. There may be additional risks related to this study that are not yet known.

What are the possible benefits of the study?

The potential benefits of having your pacemaker programmed to 100 bpm include:

- Improvement in exercise capacity
- Improvement in symptoms

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 with heart failure in the future.

What happens when I end being in the study?
After your final office visit, your study doctor or study nurse will determine how to program the pacing in your pacemaker. No further study data will be collected or study visits will occur. At the completion of this study, you will continue to receive standard medical care.

What other treatment choices do I have if I am not in the study?
You do not have to be in this study to be treated for heart failure with preserved ejection fraction (HFpEF). You are currently receiving treatment for your heart failure according to medical care standards, and that will continue whether or not you choose to participate in this study.

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 be paid $25 per scheduled in-office visit to reimburse you for transportation and other costs that you may incur by participating in this study as well as for time you spend completing questionnaires and other study-related documents. You will receive payment after you complete the Baseline, 4 week, 8 week, and 12 week in-office study visits. The study doctor or study nurse will tell you how you will be paid.

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.

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

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.

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. If you choose to leave the study after Office Visit 2, and you are in the Treatment Group, to ensure your safety you will be asked to come in for a final pacemaker check and office visit. The same procedures and tests will be performed as would have happened during the Office Visit 4: 12 Week Follow-Up Visit/Study Exit. All of your health information collected for the study cannot be removed from the study data, and will be used as described in this consent form.

If you cannot tolerate the 100 bpm programming, please let your study doctor or study nurse know and you will be exited from the study.

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 or study nurse's instructions;
- You are unable to attend all in-office visits and phone visits scheduled with the study doctor or study nurse;
- The study sponsor, Institutional Review Board, or regulatory authority stops the study for any reason.

If this happens, you will be told and the reasons will be explained to you. Following exit from the study, you will continue to receive standard medical care.

What is the role of the sponsor's representative?

Trained Medtronic personnel may be present at the in-office study visits. The role of Medtronic personnel is to give technical support. The Medtronic personnel may use a programmer to interact with your pacemaker 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. If the study doctor has this permission, the pacemaker will be explanted and sent back to the sponsor. The sponsor will collect information from the pacemaker. 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 the 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 consent 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 Date

Statement of the Principal Investigator or authorized designee for conducting the informed consent process:

I have reviewed and discussed this Informed Consent Form with the subject.

_____
Printed name of principal investigator or authorized designee for conducting the informed consent process

_____ _____
Signature of principal investigator or authorized designee Date