Informed Consent and HIPAA Authorization for Use and Disclosure of Protected Health Information

TITLE OF STUDY: Test-No Test Implantable Cardioverter Defibrillator Trial (TNT ICD) – Pilot Study

DEPARTMENT: Internal Medicine; Division of Cardiology

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FUNDING SUPPORT: Medtronic, Inc.

SUBJECT'S NAME: _____

What does informed consent for a research study involve?

You are being invited to participate in a research study initiated by the doctors at Cooper University Hospital because you will be undergoing implantation of an implantable cardioverter defibrillator (ICD). Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team as many questions as necessary to be sure you understand this form and the study requirements. If you decide to participate, you will be asked to sign this form.

The ICD is a device that treats abnormally fast heart rhythms. The device can stop the abnormally fast heart rhythm by delivering a shock to the heart or by delivering electrical impulses and "pacing" the heart rapidly. This device also has the ability to treat abnormal slow heart rhythms by delivering similar but slower electrical impulses to the heart, again referred to as "pacing" the heart.

Your doctors have already determined that you should receive an ICD either because you have already had an abnormally fast heart rhythm called ventricular tachycardia (VT) or ventricular fibrillation (VF), or because you are deemed to be at high risk for developing these types of rapid heart rhythms in the future. The device that will be implanted in this study is made by the Medtronic Corporation, and it is already approved by the Food and Drug Administration (FDA).

Who is paying for this research and where is it being done?

This study will include up to 100 subjects from Cooper University Hospital. The doctors at Cooper University Hospital have initiated this study. Medtronic is providing financial support for the study which is being sponsored by Cooper University Hospital.

One of the co investigators (Dr. White) owns stock in Medtronic, the company that is supplying funding for this study. He has reported his financial conflict of interest to the Research Ethics Committee at Cooper Hospital. The conflict is being managed by that committee.

Purpose of the Research Study:

The purpose of this research study is to determine if defibrillation testing at the time of initial ICD implantation will improve outcome with respect to first shock effectiveness for VT or VF (rapid abnormal rhythms from the lower chambers of the heart) or mortality at 1 year compared to subjects who do not undergo this type of testing at the time of implantation. In addition, another objective of this study is to determine if defibrillation testing at the time of implantation increases post-operative complications.

Although the devices used for this study are not investigational, current labeling of the device includes a recommendation for defibrillation testing. Although some patients do not currently undergo defibrillation testing for a variety of reasons, which include medical reasons or occasionally patient preference, the majority of patients still undergo this type of testing in the United States. In addition, subjects who enroll in this study will be "randomized" to receive defibrillation testing or not to receive this testing. The randomization will be like the flip of a coin, with a 50:50 chance of you being in either group. After selection, you and the doctors will know which group you belong to. Therefore, the study is considered "investigational" or "research."

What are the procedures associated with the research study?

The ICD device is implanted surgically. The procedure involves the surgical insertion of the device followed by testing of the device performed during the operation. The surgery involves placement of a device under your skin and insertion of one or more wires into the heart through

veins under the collar bone. These lead(s) are placed into the heart using X-ray guidance. The leads are then connected to the device or ICD "pulse generator." The type and number of leads inserted will be determined by your doctor based on your particular heart condition. The manufacturer of the ICD pulse generator is Medtronic, but the specific type of ICD will be determined by your doctor, based on your specific needs. Possibilities include a device which is connected to one, two or three leads. These devices are referred to as "single chamber," "dual chamber," or "cardiac resynchronization therapy" devices, respectively. All of these devices and leads are currently approved by the FDA and are not considered investigational. After the surgical procedure the device is typically "tested" at the time of implantation. The device is tested to determine how much voltage is needed to adequately pace the heart by delivering electrical impulses. This testing involves evaluation of the pacing and sensing parameters, where the size of the signal from your heart is measured and the impedance or resistance of the lead is measured. A pacing threshold is also measured which determines how much voltage is needed to adequately pace the heart by delivering electrical impulses. This portion of the testing will be referred to as "pacing evaluation" throughout the remainder of this consent form, and is considered basic testing and standard of care.

In addition to the pacing evaluation, most patients typically undergo something called "defibrillation testing." This is a more extensive testing where the heart is intentionally put into a very rapid rhythm called "ventricular fibrillation" or "VF." This rhythm is induced by delivering a very low energy shock to the heart or by pacing very fast in the lower chamber of the heart. The device is then expected to detect this abnormal rhythm and shock the heart back to normal. If the shocks delivered through the device are ineffective, the heart is then externally shocked using what is called an external defibrillator. This type of testing is often repeated 1 or more times. At our center, we typically perform 2 of these tests, unless more are needed. Most patients undergoing ICD implantation currently undergo this "defibrillation testing" in the United States. It has been determined by the doctors caring for you that you are a candidate to undergo this routine testing, and you are, therefore, eligible to participate in this study.

However, the need to perform such testing has been questioned. There have been great advances in technology since the first ICD was approved in 1985, and this type of technology has greatly improved the ability of the ICD to work effectively. There is also some information available to show that patients who may not "pass" the testing in the laboratory or operating room may still receive effective therapy through the device during follow-up. Additionally, VF testing may be associated with increased risks at the time of the implantation procedure, including worsening heart failure, stroke, heart attack, or even death. Therefore, the need to perform such testing has been questioned.

Who may or may not take part in this study?

You are being asked to take part in this study because an implantable defibrillator has already been recommended. In addition, you are also considered to be a candidate for defibrillation testing at the time of the implantation procedure.

How long will the study take?

The study will last up to 3 years, and each subject will be followed for at least 1 year following

implantation.

What will you be asked to do if you take part in this study?

It has already been determined by your doctors that you should undergo implantation of an ICD and a Medtronic device has been selected. You either already had an abnormal rapid heart rhythm (VT or VF) or you are at high risk for developing this rhythm in the future. The type of device implanted will be selected by your doctor, based on your particular heart condition and needs.

Randomization:

Once you agree to undergo ICD implantation, and are considered eligible for this research study, the study doctors and study team will offer you participation in this research study. If you agree to participate, you will be randomized to either "Group A" which is the group of subjects who will receive standard defibrillation testing at the time of implantation vs. "Group B" which is the No Defibrillation Testing group.

If at any point in the study the doctors caring for you feel that you should be in the other group, they may alter treatment if it is felt to be in your best interests or safety. This might occur at the time of implantation. For example, if your blood pressure is too low, testing might be deferred and not be performed at the time of implantation. In very rare cases, things may change with your heart or medicines, or your doctor might be concerned about some readings from your device at follow-up, and your doctor might elect to perform defibrillation testing at a later date after implantation. You would still be followed as part of the study in the usual manner. However, the results of the study will still be analyzed based on the initial group you were randomized to.

Implantation procedure:

Standard implantation techniques for ICD insertion will be followed, with devices implanted in the left pectoral region (or left chest, under the left collarbone). A standard antibiotic will be administered within 30 minutes prior to the procedure, which is routine pre-operative care.

Leads will be inserted through vein(s) under the collarbone and advanced to the heart using X-ray guidance. These leads will be connected to the ICD pulse generator. All patients will undergo standard "pacing evaluation" which includes a determination of sensing of the signal during the underlying rhythm (such as "sinus rhythm" or "atrial fibrillation") and an evaluation of pacing impedance (or resistance through the lead). The "pacing threshold" or voltage needed to pace the heart using electrical impulses delivered through the leads will be tested in all patients. These tests are considered standard for all device implants.

After the "pacing evaluation" has been determined to be adequate, the research part of the study begins.

- For those randomized to Group A, Standard defibrillation testing will be performed. After you are asleep with heavy sedation, using medications infused through a vein, ventricular fibrillation (VF) is induced through the device. A shock through the device is delivered, in an attempt to

convert the rhythm back to normal. If this does not work, other internal shocks through the implanted device and/or external shocks using an external defibrillator will be delivered to get the rhythm back to normal. (It is very unlikely that medication will be needed to help convert the rhythm, but these will be available, if necessary.) The goal is to achieve at least a 10 joule safety margin for defibrillation. This means that effective conversion of VF back to the normal rhythm should occur at a minimum of 10 joules below the maximum output of the device. For example, if the device delivers a maximum of 35 joules, energy of 25 joules should be obtained for effective conversion. It is recommended that 2 tests be performed with effective conversion of the abnormal heart rhythm using 25 joules, to allow implantation of a 35 joule device.

If this 10 joule safety margin cannot be obtained, revision of the system is recommended. There are several options, which may include moving a lead, changing the way the device delivers energy to the heart, electrically removing a portion of a lead from the shocking system, or adding an extra lead or leads under the skin on the left chest wall. The specific alternatives will be left up to the doctor implanting the device, depending on which technique is felt to be best for you.

If an adequate safety margin cannot be obtained, anticipated to occur in less than 2% of cases, your doctor may decide to end the procedure and bring you back the next day for further testing. If at any time your doctor feels you are too sick or unstable to undergo further testing, this testing will be stopped or omitted.

- For those randomized to Group B, the No Defibrillation Testing group, routine pacing evaluations will be performed, but VF will not be induced at the time of implantation. The "pacing evaluation" will help to assure that all connections of leads to the device (or ICD pulse generator) are intact. As it is currently the "standard of care" for most centers to perform defibrillation testing at the time of initial ICD implantation, the absence of such testing is considered "experimental."

Device programming:

All subjects will receive a "high output" (35 joule) device. In both groups, all shocks in the VF zone (which is the faster zone of the device, where the most rapid heart rhythms are detected) will be programmed to maximum output. Other parameters will be programmed at the implanting doctor's discretion.

Post-operative care:

You will receive routine post-operative care following ICD implantation. This will include short-term routine post-operative antibiotic administration. A routine post-operative chest X-ray and an electrocardiogram (or ECG, which records the electrical activity of the heart from leads placed on the skin) will be performed. These are standard procedures performed post-implantation and are not separate requirements for his study.

Follow-up:

You will be followed at 1, 3, 6, 9 and 12 months, and data will be collected every 6 months thereafter. This is a routine schedule for device follow-up, and is not unique to this study.

Enrolled subjects may be followed for up to 3 years (with a minimum follow-up of 1 year)

At the time of in-office follow-up, the device will be "interrogated" with a programmer (which is a special computer which can obtain information from your device). A wand may be placed over your device to obtain this information, although many devices can now be interrogated without the need for a wand.

Remote ICD follow-up may replace routine visits after the 3 month visit. This is an internet based system where the device can be interrogated from your home, using your phone line. (This is not an investigational procedure, and has now become part of routine ICD follow-up.) When you are not seen in the office during these remote ICD follow-ups, the study coordinator will contact you by telephone to obtain information regarding how you feel, any changes in your medical regimen, and any new interim medical history or adverse events. In addition, all shocks and any loss of consciousness episodes should be reported immediately. This will lead to additional device interrogations within 24 hours, or sooner, if your doctor determines this is needed. Your doctor may also decide that you should be seen more urgently, depending on what your device interrogation shows or how you feel. If you ever receive more than one shock in a row, or do not feel well after receiving a shock (such as experiencing chest pain, shortness of breath, continued palpitations or heart racing, or persistent dizziness), you should be seen immediately in the emergency room.

Other than obtaining an interim medical history and description of how you are feeling in between visits, there are no procedures or visits performed exclusively for research purposes during study follow-up.

Although it is highly unlikely that you will die during the period of time this study is conducted, this consent form will also give permission for the study team to obtain an interrogation of the device post-mortem, if feasible. This means that the device can be interrogated even after death with a wand placed the generator, without the need to remove the device. Unexpected events, new medical conditions, or accidents may occur unrelated to this study. However, verbal permission can also be obtained from your family, if this situation arises unexpectedly.

Summary of follow-up schedule:

- 1, 3, 6, 9, 12 months in all subjects, and then data will be collected every 6 months thereafter, until the completion of the study (for up to 3 years)
- Remote ICD interrogation may replace in-office follow-up visits after the 3 month visit
- History, to include questions regarding symptoms of palpitations (or heart racing), dizziness, loss of consciousness, or near loss of consciousness at each office visit or telephone follow-up
- Any change in medicines will be recorded at each office visit or telephone follow-up
- Physical exam, including vital signs at each in-office visit
- ECG or electrocardiogram (recording of the electrical activity of the heart by placing leads on the chest) at each in-office visit

What are the possible risks or discomforts if you take part in this study?

The ICD implantation is a surgical procedure and is associated with risks, outside of participation in this study. All routine surgical risks will be reviewed with you. Major life – threatening complications associated with surgery occur in approximately less than 1% of cases. Some of the risks associated with the implantation procedure may be associated with the defibrillation testing portion of the procedure. These may include stroke, mini-stroke which is known as TIA or transient ischemic attack (all which occur due to an interruption in the blood flow to the brain), heart attack, heart failure, persistently low blood pressure, and shock. There may also be delivery of multiple shocks to treat recurrent VF (which is a very rapid and irregular heart rate). It is possible that these risks may be higher in those patients undergoing defibrillation testing when compared to those who do not undergo this type of testing, although this is currently unknown. Indirect complications related to defibrillation testing may also occur and could be related to a more prolonged procedure or additional attempts at lead access or revision to obtain an adequate defibrillation threshold. Potential indirect complications may include pneumothorax, (air in the chest cavity surrounding the lungs), lead dislodgement, lead perforation, tamponade (compression of the heart caused by blood or fluid in the sack surrounding the heart), increased volume or fluid administration during defibrillation testing which may increase the chance of congestive heart failure or "fluid build-up in the lungs," adverse reactions to drugs used for enhanced sedation during defibrillation testing, skin burns from external shocks which could be required if the internal shocks are ineffective, increased risk of infection, or prolonged hospital stay.

There may also be additional risks associated with the medications administered for intravenous conscious sedation, and it is possible that these risks may be higher in patients who require more extensive anesthesia that is often required for defibrillation testing. Risks potentially related to deeper sedation utilized for defibrillation testing may include an increased risk of hypotension (low blood pressure), heart failure, aspiration (secretions or stomach contents backing up into the lungs), pneumonia, potentially requiring intubation (placement of a breathing tube to help with oxygenation of the lungs), or allergic reactions to the variety of medications used for heavy sedation.

One of the goals of this study is to determine whether or not the early complication rate (within 90 days) is higher in those patients who undergo defibrillation testing, when compared to those who do not have this testing performed.

In addition, it is currently unknown whether or not subjects who have defibrillation testing will have a better long-term outcome when compared to those who do not have this testing done at the time of ICD implantation. It is possible that the group who does not have this defibrillation testing done initially may have a lower shock success rate than those who undergo this type of testing at the time of ICD implantation, and that the first shock or even subsequent shocks might not work. These devices are able to deliver up to 5 shocks for a single event, and it is possible that it may take more than one shock to change the rhythm back to normal. If none of the shocks work, death could occur. In very rare situations, estimated to be less than 1-3% of cases, shocks may not be able to change the heart rhythm back to normal, even when defibrillation testing is done at the time of implantation. Therefore, there is never a 100% guarantee that shocks will be

effective after you leave the hospital. This is because there are many other things that could affect the ability of the device to change the heart rhythm back to normal during outpatient follow-up. These include, but are not limited to worsening heart muscle function, new heart attacks, heart failure, and certain medications. Although no one can absolutely guarantee that a device will be 100% effective, even when defibrillation testing is performed at the time of ICD implantation, multiple studies have shown that devices are still very effective in preventing sudden cardiac death in the majority of cases, with sudden cardiac death estimated to occur in only 1-3% of patients during long-term follow-up.

Research may also involve risks that are currently unforeseeable.

What if you are pregnant?:

You will not be considered a candidate for this study at the present time if you are pregnant. (In fact, you may not even be considered a candidate for "elective" ICD implantation outside of this study if you are pregnant, due to potential risks to the unborn fetus.) Radiation exposure plus drugs administered during the procedure for sedation could cause harm to an unborn child. In addition, defibrillation testing could potentially cause additional harm to the fetus, as it results in a momentary loss of blood pressure and could cause reduced oxygen and blood delivery to the fetus during testing. Therefore, women who are pregnant cannot participate in this study. In a rare situation, an ICD may be recommended to a woman who is currently breast-feeding. If you have recently delivered a child and are currently breast-feeding, you would need to dispose of breast milk for several days following implantation of the ICD, as medications administered during the procedure will likely be passed into the breast milk, and this could harm your baby. Your health care provider will provide you with specific recommendations if you are currently breast-feeding. It is also possible that harmful side effects that are not yet known could happen to both the mother and the unborn fetus or breast-feeding child. In addition, other unknown risks to the fetus associated with ICD shocks during follow-up cannot be excluded.

Reproductive risks:

If you are currently pregnant, it is important that you inform the study doctor because you will not be able participate in the study. If you are a woman of child-bearing potential, you will be given a blood pregnancy test before entry into the study. This is a routine test performed prior to ICD implantation in women of child-bearing potential. You are asked to use a medically accepted method of birth control (such as oral contraceptives or barrier methods plus spermicide) while you participate in the study. If you do become pregnant during the study, you must tell the study doctor and immediately consult an obstetrician or maternal-fetal specialist.

Are there any benefits if you take part in this study?

There may be no personal benefits to you for participating in this study. However, the information gathered in this study will add to the understanding of device testing for future patients undergoing ICD implantation, and medical science may benefit from your participation.

What are your alternatives (other choices) if you do not take part in this study?

Your participation is voluntary. The alternative is not to participate in this study. If you choose not to participate, your doctor will perform the ICD implantation according to the current standard of care (that which is normally done for patients with your condition) which will likely include routine defibrillation testing, unless your refuse to undergo this testing. You should discuss the alternatives with your personal doctor.

Will you be paid for being in this study?

You will not receive any money for taking part in this study.

Will there be any costs for you participating in this study?

As a participant in this study, there will not be any additional cost to you. All tests and procedures, as well as the cost of your device implantation, will be the responsibility of you and your insurance company.

There are no additional procedures or tests involved in this study that are not already a routine part of the ICD implantation procedure. In addition, the follow-up schedule and device testing which are a routine part of ICD follow-up and are not specific to this study.

You and your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

What happens if you are injured or hurt during the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Study Doctor listed on page one of this form. You may also contact your own doctor, or seek treatment outside of Cooper University Hospital. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at Cooper University Hospital. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

If you become injured or ill because you took part in this research study, you will be given the medical care that you need, but it will not be free. Your insurance will be billed for the medical treatment. You will be billed for the costs your insurance does not cover. There are no provisions to provide any other form of compensation. That does not mean that you are giving up any of your legal rights.

If you believe that you have been injured or become ill because you took part in this study, you should call Carolyn Bekes M.D., Senior Vice President for Academic Affairs/Chief Medical Officer or her representative at 856-342-2940 or 856-963-3835.

When is the Study over? Can you leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care. If you elect to withdraw from the study at any time, you should still receive routine ICD follow-up, which is recommended every 3 months.

If you decide to withdraw from the study after starting to participate, we will keep the information we have collected up to that point, but will not collect any additional information from you without your consent. We may, however, want to determine your vital status after you drop out of the study. To be able to determine your vital status (and if deceased, cause of death), we will consult sources of information such as the National Death Index.

How will information about you be kept private?

Information about you related to this study will be kept as private as possible. A study number will be used instead of your name on all of your study forms. The study doctor may need to let other people look at your records, but only the study doctor and the study staff will be able to link your study number to your name. (See the HIPAA authorization for the list of people who may need to inspect your study records and the reasons they need to look at them.) The list linking subjects' names and study numbers and subjects' study files will be kept in a locked cabinet in the study doctor's office.

Medtronic will keep your health information confidential in accordance with all applicable laws and regulations. Medtronic may use your health information for purposes such as overseeing and improving the performance of its devices, 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. For information received during the study your name will not be placed on any mailing lists or sold to anyone for marketing purposes. Medtronic may disclose your health information to the US Food and Drug Administration (FDA), as well as to other US 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.

Who should you contact if you have questions?

You should call Carolyn Bekes, MD, Senior Vice President of Medical Affairs/ Chief Medical Officer/ or her representative at 856-342-2940 or 856-963-3835 (a) if you have any questions about your rights as a research subject, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) if you have any complaints about the research.

If you have any questions about the research, you may contact the investigators listed on the front of this consent form. They are responsible for the conduct of the research at Cooper Hospital. They are affiliated with the Cooper Health System. Their address is One Cooper Plaza, 4th Floor, Dorrance Building, Camden, NJ 08103.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is Suite 504, 3 Cooper Plaza, Camden, NJ 08103. The phone number is 856 968-8459.

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

What will happen if you do not wish to take part in this study?

You do not have to be part of this study. If you decide to be in the study, you may quit at any time. If you decide not to participate or to drop out of the study, your decision will not affect your care at Cooper Hospital either now or in the future. Either way, the doctors at Cooper Health System will treat you the same way.

Will you be told about new information that might affect your decision to take part in this research?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

HIPAA AUTHORIZATION: Authorization to Permit the Use and Disclosure of Health Information (Protected Health Information) for Research Purposes.

Why are you being asked to sign this form?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law

gives subjects in research studies certain rights about their protected health information. Protected health information is information about a person's physical or mental health that can be identified with or linked to that particular person. As a subject in a research registry, you have the right to know what health information will be used and created about you, how this information will be used, and who will be able to see the information. You also have the right to see your own health information. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your health information for this research study. The Principal Investigator, Andrea M. Russo MD, or her Study Coordinator will be happy to answer any questions you may have regarding this form.

What information will be collected from you for use in this registry?

If you decide to be in this study, the following health information will be collected from you: medical history, results of the electrocardiograms, information and reports from your pacemaker or ICD procedure. This information is being collected as part of the standard of care and would be gathered as part of the pacemaker/ICD procedure whether or not you participated in the study.

New health information will be created about you. The new information will include the report from your pacemaker/ICD procedure, electrocardiograms, medical history, and the information which is gathered at your follow up visits. This information will be placed into your research study files and medical records. These files and records will be stored at the Study Doctor's research office, located at The Cooper Health System, One Cooper Plaza, 4th Floor, Dorrance Building, Camden, NJ 08103.

The investigators will also record health information from hospital records and/or records in the subjects' physician's office or other healthcare provider now and in the future.

How will your health information be used and disclosed?

The information described above will be used to determine your eligibility for participation in the study and to collect data through your completion of participation in the study.

In addition to the investigators listed on the first page of this form and their research staff, other people in the Cooper Health System (CHS) will be able to see your health information (described above) related to this research study. The other people are described below.

There is an Institutional Review Board (IRB) that oversees research in the CHS. People who represent this IRB may review your health information because they need to see how the study is going.

Other people who work for the CHS or its affiliated health care providers may look at your health information for the following reasons: (1) They need to fulfill orders (made by the doctors) for hospital and health care (2) they need to address correct payment for tests and procedures ordered by the doctors. (3) They need to perform internal hospital operations (e.g. quality assurance).

People outside the CHS from the agencies described below will also be able to see your health information under certain circumstances. These other people outside the CHS understand how important it is to keep your health information confidential. However, the CHS cannot guarantee that your information will be kept confidential after it has been given to people outside the CHS. The federal privacy rules do not cover any disclosures of your health information by these other people and agencies described below.

A federal agency called the Office of Human Research Protection (OHRP) oversees the CHS IRB. People from OHRP may also review your health information because they need to see how the IRB is doing.

People, who work for Medtronic, Inc. and/or its consultants, will look at and/or receive copies of your health information. People who work for Medtronic, Inc. will be present during some of your procedures.

People who work for the U.S. Food and Drug Administration (FDA) and governmental agencies in other countries may see and/or receive copies of your health information. They need to make sure the research data are accurate. They also need to be sure that the investigators, research staff, and the CHS IRB are following FDA regulations or other governmental regulations.

In unusual cases, an order from a court of law may require the investigators to release your health information. This information may include your registry records and other medical record information. State law may require the investigators to inform the appropriate agencies if the investigators learn that you or someone with whom you are involved is in serious danger or potential harm.

Will you have access to your health information resulting from participation in this research study?

You may already have a copy of CHS's Notice of Privacy Practices. If you do not have one, the investigator will give you one. This notice says that you are allowed to see information that is in your research records and medical records that are filed in the offices of your health care provider. For this research study, that means the office of the investigators and Cooper Hospital. However, you may not see your health information until the study is finished. You have the right to see information that was created as a result of your participation in this study and information that was collected and used for this research study. If you want to see this information, contact the research office at Cooper Health System, One Cooper Plaza, Camden, NJ 08103.

May you refuse to give your authorization (permission) for the use of your health information for the purpose of this research study?

You do not have to give your authorization to use and disclose your health information as described above. Your authorization is completely voluntary. However, if you do not give your written authorization for the investigators to use and disclosure your health information, you may not be in the research study.

If you decide not to allow the investigators to use and disclosure your health information for this research study, it will not affect your care at CHS, it's affiliated health care providers, or hospitals now or in the future.

May you withdraw your authorization (permission) for the use of your health information for this research study?

You may decide at any time that you no longer want the investigators to use and disclose your health information. In that case, you will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you for this study. In addition, research staff will stop using your health information. They will also stop disclosing (releasing) your information to the parties described above, with certain exceptions. The research staff may have relied on information that has already been collected from you. For example, the research staff may need to use or disclose information that they got before you withdrew your authorization in order to keep the scientific integrity of the study. The study doctor also may have to use or disclose your health information to the FDA to explain why you withdrew from the study. You may also decide to give consent for the investigator to continue to collect your health information after you withdraw from the study.

If you decide to withdraw your authorization, you should give a written and dated notice of your decision to the Principal Investigator, Andrea Russo, MD, at The Cooper Health System, One Cooper Plaza, Camden, NJ 08103. This decision will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

How long will the investigators be allowed to use your health information?

The investigators may continue to use and disclose your health information for the purposes described above for an undetermined period of time. If you sign this form, you authorize the use and disclosure of your information for this registry at any time in the future.

VOLUNTARY PARTICIPATION

I voluntarily consent to take part in this study. The study staff has discussed this research study with me. I have had adequate time to read this form and to ask questions about it. I understand by signing this form I am not giving up any of my legal rights. I am also giving my permission for use and disclosure of my protected health information. I will be giving a copy of this consent form for my records.

SUBJECT

Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

WITNESS

Printed Name of Witness to Subject's Signature: _____

Signature: _____ Date: _____ Time: _____

INVESTIGATOR

I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____