Consent Form

SUDDEN CARDIAC DEATH IN HEART FAILURE TRIAL
RANDOMIZED TRIAL FOR THE PREVENTION OF CARDIAC DEATH

INVESTIGATORS	POSITION	DEPARTMENT	PHONE
- - -	- - -	- - -	- - -

Insert your institution's communication numbers and study principals here.

24-Hour Emergency Telephone: ### - #### (Ask for any of the above physicians or nurses.)

INVESTIGATORS' STATEMENT

PURPOSE AND BENEFITS

The purpose of this research study is to compare three treatments for abnormal heart rhythms in weak hearts to see if the rate of sudden death is changed. This research study will last for up to five years.

There are two usual causes of death in people with decreased heart strength. The first cause is a progressive heart muscle weakness. This can eventually lead to complete heart failure. The second cause is a severe heart rhythm problem. This study will examine whether treatments can reduce deaths from the second cause.

There are two types of severe heart rhythms. The first type is a very slow heart rhythm called **bradycardia**. The second type is a very fast and disorganized heart rhythm called **ventricular fibrillation**. Both reduce the heart's ability to pump blood. The second type of heart rhythm is the central point of this study.

People with decreased heart strength can also die from progressive heart muscle weakness. In this study, your doctor will make every effort to improve the strength of the heart muscle to prevent death. Your doctor will use standard (well-accepted) treatments for this problem. The study will not change this treatment.

This study will compare three groups: 1) standard heart failure treatment, 2) standard heart failure treatment plus a drug to prevent bad heart rhythms, and 3) standard heart failure treatment plus a device placed in the heart to treat bad heart rhythms. The name of the drug is amiodarone. The use of this drug in this study is investigational. The device in this study is fully FDA approved but its use for this indication

is investigational. The Federal Drug Administration (FDA) regulates the use of this device. The FDA allows its use only in research. Amiodarone has been helpful in treating people with bad heart rhythms.

PROCEDURES

There will be 2500 patients for this study throughout the U.S. and Canada. If you agree to be in this study, you will receive one of three forms of treatment. Chance will decide which one. You have a one in three chance of any one treatment.

If you agree to be in this study, you must complete the 6-minute walk test at the beginning and every 6 months thereafter throughout the course of the study. This is a test to find out how far you can walk in 6 minutes. You will walk from one chair to another chair, at a set distance apart, continuously without pausing as many times as you can in the 6-minute period. If you need to, you can stop and rest, and then continue on when you are ready. The most important part about this test is that you cover as much distance as possible in the 6 minutes.

One of the choices is to provide only the **standard treatment** for heart weakness. This is the same treatment used for anyone with your kind of heart problem. There is no finding that this treatment can reduce death from bad heart rhythms. If you are assigned to this branch of the study, you will continue with your present treatment. Along with standard heart treatment, you will take a pill which contains no drug (placebo.) Neither you nor your doctor will know if this pill is a real drug or the placebo pill. Therefore, your doctor will provide care as though you are taking a drug for bad heart rhythms.

The second choice is to provide the standard treatment for heart weakness and add a medicine to prevent bad heart rhythms. The name of the medicine is **amiodarone**. If you enter this branch of the study, your care will not change unless it is necessary. Amiodarone comes in 200 mg pills. The dose of amiodarone will be a range of 400 milligrams (mg) a day (2 pills) to 800 milligrams (mg.) a day (4 pills) for one week. This will be followed by 400 mg. (2 pills) for three weeks. Thereafter, the daily dose will be dependent on your weight: 200 mg (1 pill) a day for patients weighing less than 150 lbs; 300 mg (1½ pills) a day for patients weighing between 150 and 200 lbs; and, 400 mg (2 pills) a day for patients weighing more than 200 lbs. Your doctor will not know if this pill is real drug or a placebo pill. Therefore, he or she will provide care as though you are taking a drug for bad heart rhythms.

The study doctors will manage these first two branches of the study in the same way. Since they will not know if there is an active drug, they will ask you to have some tests done from time to time. Sometimes, the drug (amiodarone) does have some side-effects. Your doctors will watch certain tests. These tests make sure that there is no change in your general health. These tests are part of this study.

The third of the choices is to continue standard treatment for heart weakness and to use an **automatic rhythm device**. In this branch of the study, your doctor will connect a device to your heart, an automatic implantable defibrillator (ICD), to treat bad heart rhythms. If you have a bad heart rhythm, the device will be able to correct the rhythm. People who had bad heart rhythms once and are likely to have them again use this device. In the past, this type of device has not been used to treat your type of heart problem. The device provides a known protection from bad rhythms. It has a “memory” to record any bad heart rhythms. Your study doctor will have you sign a separate consent form for this device. The procedure to place the ICD into your heart will take approximately 2 hours. The length of time you will need to be in the hospital for this procedure is approximately 23 hours. The ICD will need to be changed approximately every 6 to 8 years depending on whether or not you use it. Your doctor will discuss replacement with you

when the time comes. If you need your ICD replaced, there is minor surgery involved. The surgery involves making a small incision over the ICD pocket in the shoulder area, checking the ICD system, removing the old ICD, and replacing it with a new ICD.

The study doctors will see everyone, in every branch of the study, at one week, one month, and three months after entry into the study. The schedule thereafter will be every three months. The study group will schedule most visits during your regular clinic visits. At these visits, your study doctor or one of the study nurses will meet with you. On some visits, you will have some blood tests specifically for this study. Some of these tests may be part of your regular care. The blood tests require a needle stick and about 4 tablespoonsful of blood. The study can use these results, so there should be no duplication. If you are on blood thinner therapy (e.g. Coumadin, warfarin) and/or digoxin therapy a blood test two weeks after the start of the study therapy will be done to monitor blood thinner and digoxin levels.

If you are a woman of child bearing potential, a pregnancy test will be done. You must also use a reliable method of birth control before you enroll in the study. The reliable method of birth control must be ongoing throughout the study. The drug Amiodarone can cause harm to a fetus, therefore, if you are a woman and plan on becoming pregnant you should not enter the study.

The staff of (*enter your hospital name here*) and/or representatives of the SCD-HeFT Coordinating Center at Duke University may contact your doctor(s) and hospital(s) to obtain copies of your medical bills for up to 5 years (the length of the study.) When you are enrolled in the study and at 3 months, 1 year and 2.5 years after enrollment, they will ask you questions to see how you are doing and help provide information about your treatment. Some of the questions are of a sensitive nature. The questionnaires take about 20 minutes. You may refuse to answer any question. You may be asked to have your interview audiotaped in order to ensure standardization of interviews across study subjects. No identifying information will be included on the tape. The tape will be sent to the SCD-HeFT Coordinating Center at Duke University for analysis.

To be part of the study, the study doctor must have you sign a standard hospital defibrillator surgery consent form as well as this consent form before finding out which branch of the study you will enter. After you sign the consents, the study nurse will forward your name to the coordinating center at Duke University in North Carolina. By chance (one in three,) the Coordinating Center will place you in one of the branches of the study. You will then receive that treatment. You or the study doctor can not affect the choice of treatment. You will not know which treatment until after you enroll in the study.

POTENTIAL BENEFITS

Amiodarone and the automatic rhythm device (ICD) have been beneficial in treating bad heart rhythms. We do not know if you will benefit from taking part in this study. However, in addition to your regular health care providers, your study team will monitor your well-being very closely. The team will inform you of any results that the study may produce. This information may allow you to make better informed decisions about your health care management.

RISKS, STRESS OR DISCOMFORT

Some of the requirements of this study may cause some discomfort. There are some additional risks involved with being in this study. This part of this form will explain some of these extra concerns.

If you, by chance, enter the standard heart treatment branch of the study, your risk is the same as regular medical care. You will continue to receive all the standard care you would regularly receive. You will receive no additional care for the prevention of bad heart rhythms. The study doctor will monitor your health through certain lab tests and the questionnaire. Your study doctor or nurse will need to see you sometimes. These appointments may not be part of any other medical visits. These appointments take about 30 minutes. When possible, your study doctor will work with your heart doctor so you can have these visits and tests at the same time. This will keep any discomfort and inconvenience to as little as possible.

If you were to become ill and your heart doctor was concerned that the rhythm medicine used in the study could be the cause, the study managers would be able to find out what you were taking (placebo or amiodarone.) Then your doctor would know if a drug is used or not. This would be done for emergencies only.

If, by chance, you enter the drug (amiodarone) branch, there are certain risks. Doctors have used amiodarone for over 15 years. Previously, it was used only for life threatening heart rhythms. Presently, its use has grown. Physicians now use this drug for the treatment of less serious heart rhythms (atrial fibrillation). Some people using the drug have developed side effects. The side effects include skin rashes and changes in skin color (a slight bluish discoloration around the cheeks and mouth.) Abnormalities of liver and thyroid function, muscle weakness, bowel changes (constipation), and nerve problems, including fatigue, tremors, or poor coordination. Sensitivity to light and deposits on the surface of the eye that do not change vision are other side effects. There have been changes in the lungs causing a cough and a congestion like pneumonia. Unless the drug is stopped, these side effects could possibly lead to severe lung problems or even to death. This complication is rare in patients using the drug at this dosage. Since your doctor will not know if you are on amiodarone, your study doctor will watch you for these side effects. If there is any hint that you might be having any of these side effects, the study managers can find out what you were taking (placebo or amiodarone.) If you are on amiodarone and your doctor feels it is the cause of your symptoms, your doctor will stop the drug or decrease the dose. Most of the side effects go away after stopping the drug. The lung problems could continue even after the drug is stopped. Finally, there is some concern that in extremely rare circumstances, amiodarone may lead to marked visual impairment and blindness.

Whether you enter the “no drug” branch or the “amiodarone” branch, the doctors will need to watch your health. This will require some extra tests. Some of the tests are blood tests. There is some pain from the needle stick to collect the blood. This will help your doctors know if you are doing well or having any side effects from the drug. It also will be necessary to have x-rays of your chest from time to time. Your regular check-ups require most of these x-rays. The skin entrance radiation exposure from one chest x-ray is 30 millirems (a unit of radiation exposure.) You will have 2 x-rays for this study. By comparison, the natural background radiation in Seattle over one year is 300 millirems. Whenever possible, your study doctor will work with your heart doctor so tests can be done at the same time. This will keep any discomfort and inconvenience to as little as possible.

If you enter the device (defibrillator) branch, there are different risks. The insertion of the device requires a surgical operation. There are risks from this procedure that are not part of the other branches. There are risks associated with the use of an anesthetic. There are risks of infection from the operation. There are risks that the leads could cause damage to the heart or cause a bad heart rhythm during insertion. To test the device itself, the study doctor must cause you to have a bad rhythm (ventricular fibrillation.) To better explain all the risks, there is a separate, standard hospital consent form used by your doctor. Any of these

risks could cause serious injury or even death. An infection could cause the removal of the device. There is an extremely small chance of any complication, but the risk is not zero. You and your family should read all of the information about the device. You and your family should discuss this procedure with your study doctor before signing these consent forms.

OTHER INFORMATION

Your study records will be kept confidential. In addition to the investigators, the manufacturer of the device (Medtronic, Inc.,) the manufacturer of the drug (Wyeth-Ayerst,) the Food and Drug Administration, and the National Heart Lung and Blood Institute have the right to review study records. They may review information from your medical chart as it relates to this study. This information will be kept by the investigators for 7 years. The type of information needed are results of laboratory tests, chest x-rays and clinic visit notes. This information is used to outline the type of heart weakness your have. It also reflects how any treatment for your condition affects your general health.

You may refuse to participate and may withdraw from the study at any time. If you do, there will be no penalty or loss of benefits to which you are otherwise entitled. We will inform you if we learn any new information that might affect your decision to take part in this study. The alternatives to this study are not to take part in this study and receive standard care from your physician.

If you are injured or have questions about this study, your doctor or nurse will be able to answer any questions you might have throughout the duration of the study. You may call any of the doctors or nurses listed on Page 1 of this consent form for information.

There will be no payment to you for participating in this study. You or your insurance company must pay for tests that are part of your regular heart care and would otherwise be performed whether or not you participate in this study. If you are randomized to the ICD arm of this study, your insurer may be billed for the procedure to implant the ICD. However, the ICD itself, should you randomize to the ICD arm of the study, will be provided free of charge; you will not be responsible for this part of your care as part of this study. If you have a complication as a direct result of the ICD surgery, the investigators will treat you or refer you for treatment. The study will cover the costs of this treatment for ICD complications. However, any illness or injury related to your heart condition will not be covered by the study.

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Signature of Investigator Date

SUBJECT'S STATEMENT

The study described above has been explained to me, and I voluntarily consent to participate. I have had an opportunity to ask questions and understand that future questions I may have about the study or about subjects' rights will be answered by one of the investigators previously listed.

_____ _____

Signature of Subject Date