The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: **ST**andardized ultra-conservative **O**r **P**hysician-directed ICD programming for **SHOCK** reduction among patients on continuous flow **LVAD** support: a randomized controlled trial (**STOP SHOCK LVAD study**)

Principal Investigator: Daniel Cantillon, MD (216) 445-9220
After hours phone contact #: (216) 444-2200 and ask to speak to EP fellow on call.

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

You are being asked to take part in this research study because recently you have been implanted with an LVAD and have an ICD (implanted cardioverter-defibrillator).

The purpose of this study is to collect your medical information to evaluate if the programming of your ICD can reduce shocks for ventricular arrhythmias (VA) in heart failure patients with an implantable cardioverter-defibrillator (ICD) and left ventricular assist device (LVAD).

If you decide you want to take part in the research study, you will be asked to sign the consent section before any study-related activities are performed. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research study
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Taking part in this research study is entirely voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part in the study. Refusing participation will not involve any penalty or loss of benefit. If you decide to take part in this study, you must sign your name at the end of this form. No research study activity can be performed until you sign this form.

If your personal doctor is different than your study doctor, then your personal doctor will be informed of your participation in the research study.

Your participation in the research will last about 2 years.

Why might you choose to volunteer for this study?

You may not receive direct benefit from being in this study. However, taking part may help patients with LVADs and ICDs receive better care in the future.

Why might you choose not to participate in this research study?

You may not want to participate in this study if you do not want your device programming to be randomized.

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part.

DETAILED INFORMATION

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

This research is being done to compare two ICD programming methods (Ultra-conservative and Standard).Both methods are approved methods of programming for ICD's and are used here at the Cleveland Clinic. ICD devices have special capabilities that are referred to as programming features within the device (like a computer) that allow the device to have specific settings for different features the device can offer. ICD devices allow the heart to return to a stable, regular heart rhythm by applying an electrical shock to the heart. The ultra-conservative ICD programming attempts to minimize inappropriate shocks delivered to patients for ventricular tachyarrhythmias (VT/VF). Shocks can stop both ventricular tachycardia (VT) and ventricular fibrillation (VF) and may be considered lifesaving. VT and VF are rapid, irregular rhythms of the heart that can be life threatening. However, shocks can cause discomfort. They may also occur when unnecessary, which is known as "inappropriate" shock therapy.

How many people will take part in this study?

Approximately 280 people will take part in this study.

What is involved if you decide to take part in this research study?

If you choose to participate in the study you will be asked to sign this consent. Prior to your hospital discharge or at your first follow up you will be randomized to either physician discretion programming or ultra-conservative programming.

Randomization/Device Reprogramming:
You will be "randomized" into one of the study groups described below. A computer program will randomly place you in one of the study groups. This is called randomization and is like flipping a coin. Neither you nor your study doctor can choose the group you will be in. You will have a 50/50 chance of being placed in either group.

- If you are in group 1: your ICD device will be programmed to Physician Discretion programming
- If you are in group 2: your ICD device will be programmed to Ultra-Conservative programming

Your currently implanted ICD device will be programmed according to which group you are randomized into at your first study visit.

In the event your physician feels it is best for your device to be re-programmed during the study, he or she can program the ICD to the setting that is best for your condition. You may still remain in the study.

Follow Up
The visits for this study are standard of care meaning you would be completing these visits even if you were not part of the study. Research coordinators will review the electronic medical records each time you come in for your LVAD follow up visits to collect information for the study. If at any time during the study you or your physician feel it is in your best interest to change the programing of your device this can be done.

How long will you be in the study?

Participation is the study is expected to last 2 years, depending on your condition.

2. ALTERNATIVES
What are the alternatives to participation in the research study?

Your alternative is to not participate in this study. If you choose not to be in the study, your ICD will be programmed with standard programming and your doctor will still follow your progress in a similar manner.

3. RISKS
What are the risks of participating in the research study?

Potential incremental risk:
Depending on the group you are in and how your device is programmed, there is the potential for a fewer number of shocks, a greater number of shocks, or no change in the number of shocks you may receive.
Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Efforts will be made to keep your information confidential through the use of Cleveland Clinic's password protected computer system.

4. BENEFITS
What are possible benefits of participating in the research?

There may be no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society or science.

5. COSTS
Are there any costs to you if you participate in this study?

There is no cost to you to be in this research study. The services you will receive during this research study are considered to be standard of care that you would have received even if you were not participating in the research study and will be billed to you or your health insurance plan.

6. PAYMENT
Are there any payments to you if you participate in this study?

You will not be paid for your participation in this study.

7. RESEARCH RELATED INJURY
What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

8. PRIVACY AND CONFIDENTIALITY
What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other media without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other media without your express consent.

Authorization to Use/Disclose Protected Health Information
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth, Social Security number, and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, and other hospitals in the study. Cleveland Clinic will take steps to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Daniel Cantillon, M.D 9500 Euclid Ave Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS
Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Daniel Cantillon @ 216-444-9220. During non-business hours, weekends and holidays, please contact (216) 444-2200 and ask to speak to Electrophysiology (EP) fellow on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION
What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. SIGNATURES
Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date