The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Survey of QRS Frequency at Various Left Ventricular Pacing Sites for Cardiac Resynchronization.

Sponsor: Cleveland Clinic
PI: Dr. Mark Niebauer

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

Conflict of Interest Disclosure:
One or more of the Investigators conducting this study serve as paid speakers, consultants or advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy. If you have any questions, please ask your study doctor or call the Institutional Review Board at 216-444-2924.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research Study?

You are being asked to take part in this research study because you are undergoing implantation of a left ventricular (LV) pacing lead as part of a new cardiac resynchronization therapy (CRT) pacemaker/ICD or upgrade of an existing pacemaker/ICD by addition of a LV lead. We will be using the same leads and other standard equipment required for this study.

Why Is The Research Study Being Done?

This CRT device is being implanted to help improve you heart function and reduce your heart failure symptoms. While much is already known about generally good locations for the new lead, there are still individual patients who do not improve after CRT implant. During the implantation, there are no definite guidelines to guide the physician to the best site, since all patients have differences in heart anatomy and function. This research will collect information from different places in the left ventricle where pacing can be performed to analyze the local signals and EKG changes. This information will be used to compare the EKG differences between locations. We plan to use this information to design a system to analyze the EKG immediately at different sites that will allow the doctor to place the LV pacing lead in a place where we have the best chance of improving the heart function. All leads and devices being used in this study to collect this information are approved for general use.

How Many People Will Take Part In The Study?

Up to 40 subjects will be included in this study at the Cleveland Clinic.

How Long Will You Be In The Study?

Your study participation will be completed once your procedure is completed.

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What is Involved In The Study?

During the implantation procedure, different vein branches will be identified where the LV lead can be placed. A very thin temporary pacing and recording wire will be placed in these veins. We will pace from 3 of these veins to obtain the EKGs and signals. In each vein we will pace and record signals from 3 locations. One of the veins will be the usual "target" vein that we normally use for LV lead placement. After the information has been collected, your CRT implantation will occur.

The additional time required to collect information for this study is not expected to exceed 5-10 minutes, but there will be a small amount of additional radiation needed to position the thin pacing wire for testing. Once all of the pacing is completed, there will be no further changes to your planned CRT implantation. Your participation in the research requires no additional actions on your part. The research team will look at your EKG and echocardiogram changes that occur from before the implant through recovery and later follow-up.

2. ALTERNATIVES

What Other Options Are There?

This is a data collection study, your alternative is to not participate in this study and receive the LV lead and CRT device in the standard manner.

3. RISKS

What Are The Risks Of The Study?

The risk to this study will be the additional time and radiation exposure required to position the thin pacing wire in the two nontargeted vein branches and the time required to pace and record from the three sites. It is expected that only 2-5 mintes will be required. If too much time is needed to move the pacing wire into either of the two additional veins, we will proceed to the next step and not spend the extra time or expose you to the added radiation.

Radiation
One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer in the U.S. is about 1 chance in 5. Everyday radiation exposure from natural occurring background radiation (sun, radon exposure in the home) is approximately 3 mSv per year. In this research study, you will be receive an additional exposure of 13 mSv combined with 36 mSv performed for standard care. This radiation exposure risk is equal to an additional 4.3 years of natural background radiation.

Unforeseeable/Unknown Risks
There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

4. BENEFITS

What Are the Benefits to Taking Part In This Study?

While you will not obtain any immediate benefit from this research, the information gathered will be helpful in developing a system where we can offer patients the best chance of improvement after future CRT device implants.

5. PRIVACY AND CONFIDENTIALITY

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 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 need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best 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, Dr. Mark Niebauer, The Cleveland Clinic, 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.

6. COSTS

Are There Any Costs For You To Participate In This Study?

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

7. COMPENSATION

Are There Any Payments For You To Participate In This Study?

There will be no payments to you for participaing in this study.

8. RESEARCH RELATED INJURY

What Happens If Injury Occurs?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic or the sponsor will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

9. VOLUNTARY PARTICIPATION

What Are Your Rights As A Participant?

Taking part in this study is voluntary. If you do not want to participate, your regular medical care and legal rights will not be affected. Even if you join the study, you may stop at any time. 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.

10. QUESTIONS

Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Mark Niebauer at (216) 444-3160. During non-business hours contact the hospital operator at 216/444-2200 and ask to speak to the 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.

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	Signature of Participant	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