Date: 02-03-2022
Principal Investigator: Charles Henrikson, MD

MRI of Patients with Cardiovascular Implanted Electronic Devices

Abstract

Ferromagnetic Implants such as pacemakers and implanted cardioverter defibrillators (ICD) are traditionally accepted as contraindications to MRI due to safety concerns. We hypothesize that these procedures can be safely performed when appropriate safety precautions and vetting practices are implemented.

This is a cohort study. 4000 patients with a clinical need for MRI will be included in the study at OHSU. The type of cardiovascular implanted electronic device (CIED) and leads will be ascertained and a safety protocol will be strictly adhered to.

Background

It has been estimated that 50-75% of patients with CIED's will develop an indication for an MRI examination. Thus, there are approximately 200,000 patients annually denied MRI scans because of the presence of CIED's in the United States. The current standard of care is not to perform these scans, and instead to utilize other (inferior) imaging, and make clinical decisions without the benefit of MRI imaging. This is the current standard of care of OHSU, where only pacemaker patients who are not pacemaker dependent can undergo MRI scans, per radiology policy. However, this leads to gaps in care for some patients who would clearly benefit from an MRI scan. In some centers, it has been shown that when proper precautions are taken, MRIs can be safely performed on patients with CIED's. The published experience from Johns Hopkins reports over 2000 scans performed without any long term clinically significant adverse outcomes (Nazarian, 2017). There are also several smaller studies documenting the safe experience with MRI scanning in device patients (Nazarian, 2011, table 4).

The main concerns which have led to restrictions on MRIs in patients with CIED's are the following (Nazarian, 2009).

- Force and torque—ferromagnetic devices in a magnetic field are subject to static and gradient magnetic field induced force and torque. However, the maximum force that a modern CIED generator would be subject to is 100g, far under what would be needed to dislodge a device.
- Current induction—the gradient magnetic fields in the MRI scanner could induce current in conductors in the field. However, the maximum observed current in vitro has been less than 0.5mA, far less than what is required to capture myocardium.
- Heating—Leads and other metallic devices can act as antennae, and may heat in the magnetic field, however, no heating greater than 0.5° C were observed in vitro.
- Inappropriate pacing/shock/inhibition of pacing—CIED's have the possibility of receiving electromagnetic interference from the MRI and having this lead to inappropriate pacing, inhibition of pacing, ICD shocks, reprogramming, or loss of function.

While all of the concerns are real and have been reported in earlier generation devices, with proper patient selection and monitoring during the scan, MRIs can be performed safely on most device patients. We have the benefit of the Johns Hopkins experience of over 2000 scans without any clinically significant adverse events (Nazarian, 2017). The proposed protocol here follows exactly the 2017 Hopkins protocol. To review the most recent Johns Hopkins publication (Nazarian, 2017): 2103 MRI studies in 1509 CIED patients were reported. All MRI scans were clinically indicated, and a device clinician, familiar with device interrogation and programming, was physically present for the entire duration of the scan. All patients were continuously monitored via telemetry and pulse oximetry during the MRI. For pacemaker patients, if they are dependent they were reprogrammed to a non-sensing mode for the scan. If they were not pacemaker dependent, they were left in their usual mode. For ICD patients, if they were not pacemaker dependent, they were left in their usual mode. However,

pacemaker dependent ICD patients were not scanned, as ICDs generally do not have a non-sensing pacing mode. Tachytherapy was disabled in all ICDs for the scan.

There were nine clinical events during scans, all were “power on resets”, which means that the device resets to “out of the box” original factory settings. The first of these patients had an ICD, felt tugging in his chest during the scan, and the scan was not completed. The second had two power on resets of which one was transient and, after completing four MRIs, during the initial interrogation at the fifth MRI experienced inhibition of pacing at the examination who was within 1 month of battery remaining the device could not be reprogrammed and was replaced. The forth event was a pacer dependent patient who experienced a pause after the power on reset programmed an inhibited pacing mode. The MRI was aborted and the device was restored to original programming without any clinical consequence. The remaining5 were power on resets, in whom the scan was completed, did not noticed anything abnormal during the scan, and had normally functioning devices at follow-up.

In the overall patient population in the Hopkins study, no single patient had a malfunction of a device immediately following the scan. There was a slight change in the electrical parameters of the leads, on average, but this did not result in the need for any intervention on any patient.

Abandoned leads epicardial leads and pacemaker dependent ICD were initially excluded from previous iterations of the study:

- Abandoned leads due to the theoretical risk of increased heating at the electrode and increased risk of thermal injury to the myocardium. Abandoned leads are old leads that are left in the patient at the time new leads are implanted. Extracting them for the sole purpose of allowing an MRI to be performed is rarely done. Expanding the inclusion criteria to allow for abandoned leads will offer a higher quality imaging modality in those with abandoned leads. Several studies have demonstrated the safety of MRI in patients with abandoned leads including studies from University of Pennsylvania and Mayo Clinic in Rochester, MN (Padmanabhan, 2018, Shaller, 2021).
- Epicardial leads were initially excluded due to the theoretical risk of increased heating at the electrode and increased risk of thermal injury to the myocardium. Recent studies from Children’s Wisconsin and University of Utah have shown no significant adverse events in those with epicardial leads. (Bireley, 2020, Gakenheimer-Smith, 2020) Epicardial leads are common in children with congenital heart disease due to their size and complex cardiac anatomy. In addition, epicardial leads may be an option in adults who have poor venous access. Expanding the inclusion criteria to allow for epicardial leads offers a higher quality imaging modality in understanding cardiac anatomy and function in the setting of congenital heart disease.
- Pacemaker dependent ICDs were excluded as they did not have the capability to asynchronously pace. However, ICDs now have this function and can be appropriately programmed while therapies are disabled.

Cardiac MRI is powerful for the diagnosis of cardiomyopathies, valvular heart disease, and vascular disease. It is power lies in its ability to diagnose, prognostic, and alter medical management. The presence of CIED is associated with device-associated artifact, which may involve >50% of the myocardium. Specifically, hyperenhancement artifact related to ICD-induced frequency offset of susceptible myocardium may mimic late gadolinium enhancement (LGE) obscuring the ability to determine the extent of scar, or even falsely suggesting scar presence. There are protocols designed to offset this by utilizing different frequencies and have been used widely for many years. Those are called wideband imaging sequences, which are part of the imaging protocol. Such sequences provide better image quality, less artifact, without any adverse effect on the implantable cardiac device.

Objectives

The primary objective of this study is to develop a protocol, consistent with DHHS/CMS guidelines and requirements to further document safety in clinically indicated MR imaging in patients with CIED’s.

Date: 02-03-2022
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Study Procedure

MRI's will be conducted on patients who require a clinically indicated MRI only. All studies will be done in the 1.5 Tesla MRI unit that may use sequences to suppress the hyperenhancement artifact which results from those implanted devices, leading to improvement in the quality of cardiac MRI images and improvement in the care of patients without a known adverse event. ECG monitoring pads will be placed on the patients for the duration of the study. An external defibrillator and ACLS drugs will be on hand. Heart rate, blood pressure, O2 saturation will also be monitored non-invasively throughout the study.

All devices will undergo a complete interrogation prior to imaging. Parameters such as atrial and ventricular pacing thresholds, R and P wave amplitudes, lead impedance, and battery status will be measured and recorded. Pacemakers will be programmed to an asynchronous mode if dependent and to an inhibited mode in patients without pacemaker dependence. ICD patients will have therapy function programmed off. In addition, ICD Patients who are dependent will be programmed to asynchronous mode

There historically has also been a concern that newly implanted leads (<4 weeks) are at risk for lead to dislodgement d/t possible torque from the MRI environment. This too is only a theoretical concern and there is little or no scientific evidence to support this claim. Nevertheless, patients with newly implanted CIED leads will be considered by the PI for protocol inclusion only if the referring physician deems the MRI to be critical and after considering the risk/benefit to each individual patient.

After the appropriate MRI protocol for each MRI patient's unique condition has been completed, the device will be re-programmed to its original settings and completely interrogated to detect any changes in device performance.

The duration of the study extends up to 6 months post procedure interrogation where the patient will be recommended to be seen by their local device clinic (Nazarian, 2017).. If the CIED reveals any malfunction post imaging (not seen yet), the patient will be followed by the electrophysiology service and appropriate follow-up management will be arranged.

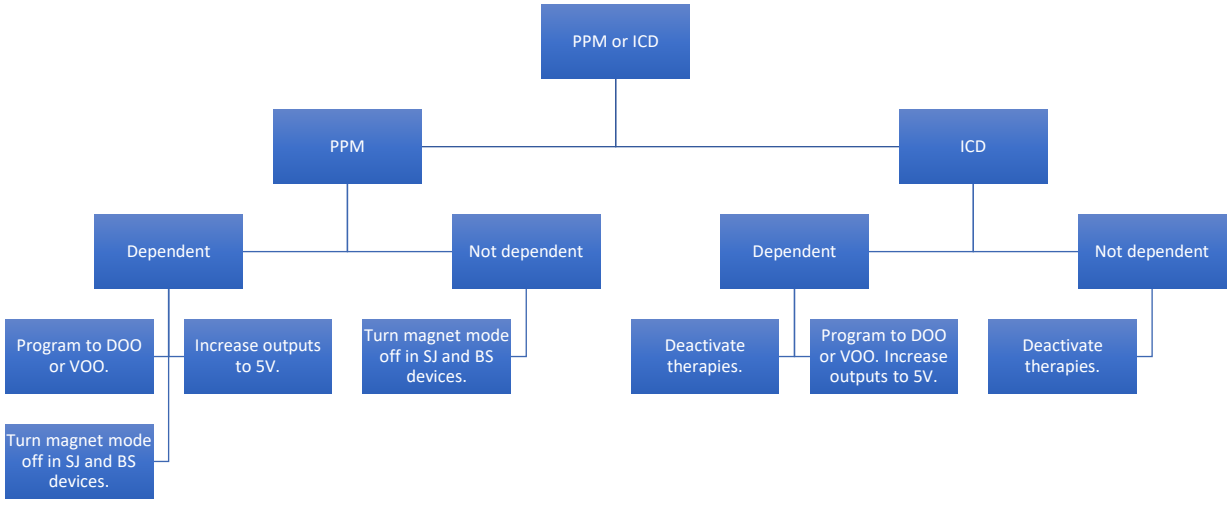

Figure 1: Clinical MRI workflow for pacemaker and ICD patient

Inclusion/Exclusion Criteria

Inclusion:

- Patients with an absolute clinical need for MR imaging and pacemakers (year 1996 model or later) or ICD's (year 2000 or later).
- Patient Age range 9-99

Exclusion:

- Patients with pacemaker models before 1996 and ICD models before year 2000.
- Patients who are unable to communicate in the scanner
- Patients who complete the MRI standard screening form and are deemed inappropriate for MRI for any reason
- Pregnant patients will be excluded in their first trimester and will not get gadolinium at any time during their pregnancy
- Patient with leads implanted <6 weeks unless the procedure is deemed critical by the referring physician and approved by the PI.

Study Statistics

Primary outcome variable.

- Patient safety and device malfunction during or after MRI

Secondary outcome variables.

- None

Statistical plan including sample size justification and interim data analysis.

- We hope to enroll 4000 patients over 4 years to further evaluate safety.

Early stopping rules.

- N/A

Data and Specimens

The following data may be stored in a repository:

- *Demographics (race, sex, month and year of birth)*
- *MRI date, diagnosis, and device interrogation data.*

Sharing of Results with Subjects

- Results will be available in OHSU's electronic medical record and may be shared with patients by study team or other healthcare providers.

Data and Specimen Banking

Data will be stored in a repository. The data will be stored indefinitely, but a yearly CRQ will be submitted to maintain the database. Future studies utilizing the repository will be subject to individual IRB submissions by the investigators.

The Principal Investigator, Dr. Charles Henrikson, will be the Guardian of the repository. As Guardian, his responsibilities are as follows:

- Ensuring that data are received and released according to OHSU policy and the IRB approved repository protocol.
- Executing a repository sharing agreement each time data is released for research purposes.
- Ensuring the security and confidentiality of stored data.
- Ensuring the security and confidentiality of data during transfer.
- Tracking acquisitions and releases of data.

Any collaborator who would like to access the data will be required to submit a proposal with a description of study objective and proposed analyses. Proposals will be reviewed by the study investigators and after approval de-identified dataset will be prepared. Data will be transferred in files using encryption. Data released to other investigators will be labeled with only the code. Additionally, a repository sharing agreement will be signed by the PI and the investigator requesting the data. Approval of the ancillary study by the IRB of the institution-recipient of the data will be required. All releases of data will be tracked by the study team and shared with the OHSU IRB during each continuing review.

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Risks

There are no studies showing any health hazards associated with magnetic field exposure. CIED's subjected to the strong electromagnetic field of MR imaging are thought to be susceptible to movement and torque. Other traditional concerns include malfunction due to demagnetization or magnetic activation leading to inappropriate pacing and shocks and artificial sensing of electromagnetic interference from MRI leading to inappropriate inhibition and/or activation of antitachycardia therapy, device malfunction and induced arrhythmias, as detailed in the background section above. Heating of the device and surrounding tissues leading to fibrosis and increased capture thresholds have also been a theoretical concern. However, recent work has revealed the safety of CIED's in the MR environment given appropriate precautions (Bireley, 2020, Gakenheimer-Smith, 2020, Nazarian, 2017, Padmanabhan, 2018, Shaller, 2021).

Appropriate measures discussed in the protocol section will be taken to minimize risks associated with device exposure to MRI. Consistent with standard MRI policy, patients in the first trimester of pregnancy and patients with history of allergic reactions to gadolinium will undergo imaging without any contrast media.

Patient data will be monitored on a per patient basis. Pre and post MRI device testing data will be compared and any significant differences immediately reported to the IRB.

Benefits

The patient will benefit from a standardized protocol to minimize the risk of an MR scan deemed necessary for their care which would otherwise be denied or performed without any organized framework. Society will benefit because of the increasing number of implanted devices and expanding use of MRI.

Costs

The patient and their insurance will be responsible for the cost of the clinically indicated MRI.

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References:

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Padmanabhan D, Kella DK, Mehta R, Kapa S, Deshmukh A, Mulpuru S, Jaffe AS, Felmlee JP, Jondal ML, Dalzell CM, Asirvatham SJ, Cha YM, Watson RE Jr, Friedman PA. Safety of magnetic resonance imaging in patients with legacy pacemakers and defibrillators and abandoned leads. Heart Rhythm. 2018 Feb;15(2):228-233. doi: 10.1016/j.hrthm.2017.10.022

Roguin A, Zviman MM, Meininger GR, et al. Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe: in vitro and in vivo assessment of safety and function at 1.5 T. Circulation 2004;

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OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 8423

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Safety of Clinically Indicated Magnetic Resonance Imaging (MRI) in Patients with Permanent Pacemakers (PPM) and Implanted Cardioverter Defibrillators (ICD)

PRINCIPAL INVESTIGATOR: Charles Henrikson, MD, MPH 503-494-7400

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE: You have been invited to be in this research study because your doctors have requested you have a MRI and you have an ICD or PPM. The purpose of this study is to develop a plan for safely and effectively performing MRIs on subjects with implanted devices.

DURATION: This study requires 2 visits; one will be at the MRI and the other will be a regularly scheduled device clinic follow up.

PROCEDURES: If you decide to take part in this study, you will get received an MRI at OHSU as your provider has ordered. The visit will include a cardiac device check before and after your visit, and your cardiac rhythm will be monitored while you are in the MRI. This visit will usually take 1-2 hours and you will follow up with your local device clinic within the next 6 months at a regularly scheduled appointment.

The study team will obtain information about the specific type of implantable cardiac device (defibrillator or pacemaker) that you have. This will allow them to read and adjust your device's settings using a computer and antenna placed on your chest. Before your MRI they will adjust your device to the best setting to tolerate the magnetic field of the MRI.

You will be attached to an electrocardiogram (ECG) while we read and adjust your device and for the duration of the MRI scan. The ECG allows us to monitor your heart rate and rhythm.

You are recommended to follow up with your local device clinic within the next 6 months. Please ask them to contact OHSU at 503-494-7400 with any questions or concerns. If your medical condition requires, you may need to have more than one MRI. If you need more than one MRI, data will be collected by the study team from each MRI scan that you have.

RISKS: You have already consented, or will soon consent to, and MRI scan. That procedure is not experimental and is not part of this study. The risks of the scan and the contrast agent dye have already been discussed with you, or will soon be discussed with you.

Your implantable cardiac device is traditionally thought to increase risk during MRI scans. Concerns about such devices include the potential of the MRI magnet to move the device or

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heat up its components. There is also some concern for device malfunction, resulting in interruption of appropriate treatments, activation of inappropriate treatments, life threatening arrhythmias (disruptions of normal heart rhythm), or the need to have your device replaced after the MRI. However, recent work shows many of these risks are avoidable when appropriate precautions are taken.

It is important for you to tell the MRI staff if you have had brain surgery, implanted medical or metallic devices, shrapnel, or other metal such as metal in your head or eye.

BENEFITS: You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES: You may choose not to participate in this study. This is a voluntary research study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 8423

Clinical Research Consent and Authorization Form

TITLE: Safety of Clinically Indicated Magnetic Resonance Imaging (MRI) in Patients with Permanent Pacemakers (PPM) and Implanted Cardioverter Defibrillators (ICD)

Principal Investigator:	Charles Henrikson, MD, MPH	503-494-7400
Co-Investigators:	Mina Mostafavifar, PA-C	503-418-5750
	Angela Krebsbach, PA-C	503-494-7400
	Anne Glover, PA-C	503-494-7400

WHO IS PAYING FOR THE STUDY? This study is being supported by OHSU Cardiology and Diagnostic Radiology

SUPPORTED BY: OHSU Division of Cardiovascular Medicine

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?
No

WHY IS THIS STUDY BEING DONE?
You have been invited to be in this research study because your doctors have requested you have an MRI and you have an ICD or PPM. ("You" means you or your child in this consent form.)

The purpose of this study is to develop a plan for safely and effectively performing MRIs on subjects with implanted devices. Traditionally, such devices have been excluded from MRIs until recently when some were designed and tested for MRI exposure. Participation in this study is the only way you can receive an MRI.

This research is being done to monitor and reduce the potential for complications for subjects with implantable cardiac devices who need an MRI. Since these devices have metal parts, they may be affected by the strong MRI magnets. Appropriate precautions may help prevent these complications and by participating in this study we hope to minimize such risks for you.

The use of the MRI on patients with some Cardiac Implanted Electronic Devices experimental. It has not been approved by the FDA because we do not know enough about it.

This study requires 2 visits; one will be at the MRI where we will check your cardiac device before and after the procedure. The other will be a regularly scheduled device clinic follow up at your local device clinic.

We are asking you to provide information for a bank, also called a repository. These samples will be stored indefinitely and may be used and disclosed in the future for research.

CO1450

About 3000 patients will be enrolled at OHSU over the next 4 years.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?
The study team will obtain information about the specific type of implantable cardiac device (defibrillator or pacemaker) that you have from your local clinic or in your OHSU medical record. This will allow them to read and adjust your device's settings using a computer and antenna placed on your chest. Before your MRI they will adjust your device to the best setting to tolerate the magnetic field of the MRI.

You will be attached to an electrocardiogram (ECG) while we read and adjust your device and for the duration of the MRI scan. The ECG allows us to monitor your heart rate and rhythm.

You are recommended to follow up with your local device clinic within the next 6 months. Please ask them to contact OHSU at 503-494-7400 with any questions or concerns. If your medical condition requires, you may need to have more than one MRI. If you need more than one MRI, data will be collected by the study team from each MRI scan that you have.

In the future, your information may be given to researchers for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WILL I RECEIVE RESULTS FROM THE MRI AND DEVICE CHECK IN THIS STUDY?

The results of your MRI with be released to your ordering provider and is not part of the study. The results of your Device Check will be placed in your medical record. While this study is still in progress, you may not be given access to medical information about you that is related to the study. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

You have been invited to be in this research study because you are scheduled to have an MRI. That procedure is not experimental and is not part of this study, and the risks will be discussed with you separately.

You have already consented to, or will soon consent to, an MRI scan. That procedure is not experimental and is not part of this study. The risks of the scan and the contrast agent dye have already been discussed with you, or will soon be discussed with you.

Your implantable cardiac device is traditionally thought to increase risk during MRI scans. Concerns about such devices include the potential of the MRI magnet to move the device or heat up its components. There is also some concern for device malfunction, resulting in interruption of appropriate treatments, activation of inappropriate treatments, life threatening arrhythmias (disruptions of normal heart rhythm), or the need to have your device replaced after the MRI. However, recent work shows many of these risks are avoidable when appropriate precautions are taken.

It is important for you to tell the MRI staff if you have had brain surgery, implanted medical or metallic devices, shrapnel, or other metal such as metal in your head or eye.

There may be risk as a result of storage of your information in a repository. Breach of confidentiality could impact insurability, employability, family plans, and family relationships. Psychological risks to consider include the impact of learning results if no effective therapy for the disorder exists or the risk of stigmatization.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

You may choose not to be in this study.

WHO WILL SEE MY PERSONAL INFORMATION?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Your information will be immediately coded and any identifiable information will be kept in a separate protected file

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository to conduct future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research. Those listed may also be permitted to review and copy your records, including your medical records.

- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

We may also share your information with other researchers, who may use it for future research studies. We will never share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

Data from this study may be shared with other investigators for future research studies. A code number will be assigned to information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your information for research will be given only the code number which will not identify you

We may continue to use and disclose protected health information that we collect from you in this study indefinitely

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You or your insurance company will be responsible for all costs related to participation in this study. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Charles Henrikson at 503-494-7400 or the cardiologist on call at 503-494-9000

If you are injured or harmed by the study procedures, you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect

compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Charles Henrikson at 503-494-7400 or members of the study team at 503-418-0990

This research has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research participants. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this study, or if you withdraw early from the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:
Charles Henrikson, MD

Oregon Health and Science University
Knight Cardiovascular Institute
3181 SW Sam Jackson Park Rd.
Mail-code: UHN-62
Portland, OR 97239
henrikson@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will destroy all your information. However, if your samples are already being used in an ongoing research

project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

You may be removed from the study if staying in the study would be harmful to you or if you fail to follow instructions. There may be other reasons to take you out of this study that we do not know at this time. If you are removed from the study early, the PI may use or give out your health information that has already been obtained.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

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.

SIGNATURES:
Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

_____ _____
Signature of Subject Date
(or Parent/Guardian if subject is under 18)

_____
Printed Name of Subject
(or Parent/Guardian if subject is under 18)

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Subjects ages 15-17:

Your signature below indicates that you agree to be in this study.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

Use of an Interpreter: Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____
Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.