CorCal Research Trial - Consent and Authorization

Title: "Effectiveness of a Proactive Cardiovascular Primary Prevention Strategy, With or Without the Use of Coronary Calcium Screening, in Preventing Future Major Adverse Cardiac Events (CorCal Trial)"

Purpose: The main purpose of the CorCal (*Coronary Calcium*) trial will be to test the effectiveness of a proactive heart treatment strategy, with or without the use of heart calcium screening, compared to present standard treatment practices, in preventing future heart disease among a moderate risk population with no present evidence of current heart disease.

Rationale*:* Heart Disease is the single largest killer of American males and females. It is estimated that 34% of all heart related deaths occur in patients with no prior symptoms. In order to help these patients, we need to identify those at very high risk, or who actually have disease without symptoms, and treat them with the most appropriate preventative therapies we can identify. Presently, we screen patients for heart disease by risk factors, using the current American Heart Association risk equation to assess heart disease risk. A predicted risk, or in other words, a percentage chance, for developing heart disease from plaque buildup in the arteries within the next ten years is calculated, and recommendations are made based on that risk model. We believe that determining the actual presence or absence of heart disease through a coronary artery calcium scan will be more effective in guiding future heart-related treatments than simply using risk factors, but this needs to be proven.

Procedures: If you choose to participate in this study, you will be placed into one of two groups at random. For example like the flip of a coin. One group will be managed by your primary care provider, based on existing heart risk factors, according to the current American Heart Association guidelines. The other group will undergo treatment based upon the results of a coronary artery calcium scan (this scan scores the amount of calcium in your arteries, which correlates with the level of plaque buildup present, and predicts one's future risk of having a heart attack or developing other heart disease). Recommendations for treatment with statins, based on the coronary calcium score, will be provided to you and your primary care provider as part of the research study.

You will also be asked to complete a questionnaire (or survey) about your medications at 3 months after enrollment into this study, and then once per year up to 4 years thereafter. These questionnaires should take no more than 5 minutes to complete and can be done online via a link that will be provided to you. If you do not have internet access, paper copies of the questionnaires may be sent to you for completion (for example, by postal mail).

In addition, your electronic medical records will be accessed throughout the study. This will be done at approximately 3 months after enrollment into this study and then intermittently thereafter for the duration of this study. If, for some reason, we cannot establish contact with you after multiple attempts and no revocation is given, we will continue to follow you via medical records for long-term outcomes.

Confidentiality and procedures*:* The data that will be collected are routine historical information and laboratory results, which are already accessible to physicians and/or nurses at Intermountain. In addition, all information and/or laboratory results will have all personal information removed prior to use for this research. The researchers will need to share your information with others who are involved in the conduct of this study, or with the individuals and/or regulatory authority who has oversight of this study (for example, the U.S. FDA and/or the Intermountain study monitors and IRB/institutional review board).

Will I be given new information during the study? Yes, the study doctors and/or your primary care physician may talk to you about new information or developments that impact your healthcare.

Risks: This study has no more than minimal risk. Subjects participating in this study will have similar risks as walking to their usual care clinic follow up visit, walking in their own home, or walking in other public places. There are only two possible study-required tests in this trial, a CT coronary artery scan and a blood cholesterol test. The CT coronary artery scan is an x-ray image of your heart to look for calcium, a procedure that is currently requested and done for selected patients in the clinical setting. Patients randomized to the coronary calcium scan in this study will be asked to have this test, which has less radiation than a mammogram. Additionally, if you have not received testing of your cholesterol in the previous 3 years, than you will be asked to go get your cholesterol tested. This is a routine procedure and risk of drawing blood includes things like discomfort, bruising, bleed/clotting, swelling, and infection. There are no research-specific medications or other procedures, though you may receive recommendations from your primary care provider based on your test results. The identifiable risk in this research study relates to issues surrounding confidentiality. Unauthorized persons could potentially access your private information. We make every effort to protect your data. Behavior risk may

include vulnerability that may occur during discovery of new information about their health condition. In addition, risk of research data ending up in the subject's medical records is also possible.

Benefits: There are no expected personal benefits for individual subjects participating in this research. However, if the researchers/investigators are successful at demonstrating the effectiveness of a proactive heart treatment in preventing future major heart events, such discoveries may permit the development of this strategy for improved and more cost-effective treatment/medical management that will benefit others in the future.

Costs: There are no costs to you for participating in this research study. If you have not had a laboratory test to check your cholesterol in the last three years, you may be required to get one as a result of participating in the trial. Both this and the coronary artery calcium scan will be billed to the study and will cost you nothing. Participants will not receive any monetary or other forms of compensation for participating in this research study.

What if I am injured because I was in the study: In the remote instance that you are injured as a direct result of participating in this study, Intermountain Healthcare can provide medical treatment. We will bill you or your insurance company in the usual way. Because this is a research study, some insurance plans may not pay for your treatment. If you believe you have been injured as a result of being in this study, please call the Principal Investigator right away. You may also contact the Intermountain Institutional Review Board (IRB) at 1-800-321-2107 or IRB@imail.org.

Are there other research projects that I can help with: From time to time, we may develop a new research project that you might like to participate in. We may contact you in the future to let you know of those opportunities.

Study contact*:* If you have any questions complaints or if you feel you have been harmed by this research please contact: *Jeffrey L. Anderson, MD, Cardiologist, Intermountain Heart Institute at 801-507-4700 or by e-mail at CorCal@imail.org.*

IRB contact*:* Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. You may also contact the Intermountain Institutional Review Board (IRB) at 1-800-321-2107 or IRB@imail.org.

Voluntary participation*:* Participation in this study is voluntary. You can choose not to take part in this study. You can choose to not answer any question you prefer. And even after enrollment, you can withdraw from this study at any time by contacting a member of the study team, without penalty or loss of benefits that you are otherwise entitled to. If you do not participate in this study or you withdraw from participation, you will continue to receive appropriate medical care from your regular clinic doctors.

By agreeing to participate in this study upon reading this letter, having all of your questions asked and answered, and by clicking the "I agree" button on this electronic consent, or by providing electronic or paper-based consent at a clinic visit if you do not have internet access, you are hereby giving your consent to participate in this study. Additionally, by consenting to participate, you are agreeing to potentially receive important study-related communication via email and/or a phone call by a member of the research study team. We want to thank you for your time and for considering participating in this study.

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Participant's Signature Date

_____ _____

Signature of Person Obtaining Authorization and Consent Date

Intermountain Healthcare IRB
IRB NUMBER: 1050633
IRB APPROVAL DATE: 07/14/2022
IRB EXPIRATION DATE: 02/09/2023