Official Study Title: Comprehensive Characterization of Coronary Atherosclerotic Disease Using Photon Counting- Detector Dual-source CT and Its Impact on Patient Management

NCT Number: NCT05240807

Document Name: Informed Consent Form : Clinical CT Informed Consent (Arm 1)

Approval Date: 7 November, 2025

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Comprehensive characterization of coronary atherosclerotic disease using photon counting- detector dual-source CT and its impact on patient management
Coronary CT Angiogram consent

IRB#: 21-004933

Principal Investigator: Cynthia McCollough, PhD

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to determine in patients the impact of the improved image quality and spatial resolution of a new type of CT scanner. This new type of CT scanner can image much smaller objects. It also can detect the energy of the x-rays that pass-through patients. These abilities improve the quality of CT images and can potentially detect areas of the heart with reduced blood flow. We are seeking to determine the impact of these improvements on the ability to accurately measure the severity of coronary artery disease. You have been asked to take part in this research because you are having a coronary CT angiogram as part of your normal clinical care. Our enrollment target is 250 over the next 2.5 years

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What's Involved	Study participation involves this informed consent form, after which you will be escorted to the Photon Counting Detector CT Scanner (PCD-CT) on the 3rd floor of the Mayo Building for a cardiac CT exam. The research cardiac CT exam will include one scan through the heart after the injection of iodinated contrast material ("x-ray dye"). It will be very similar to your clinical coronary CT angiogram. The exam will take approximately 20 minutes to complete. Once the exam is finished, you will have completed your time in the trial.
Key Information	As with all research, there is a chance that confidentiality could be compromised; however, we take several steps to minimize this risk, such as storing all patient records on secure storage drives. You will be exposed to a small amount of radiation during the cardiac CT scanning. The amount of radiation you will receive has a low risk of harmful effects. Intravenous contrast injections are associated with a small risk of kidney injury, allergic reaction, and leakage of intravenous contrast from your vein into the soft tissues of your arm. If you have had a previous allergic reaction to iodine contrast injections or have signs of decreased kidney function, you are not eligible to participate in this study. Beta blockers to reduce your heart rate and nitroglycerin to dilate your coronary arteries are routinely given for clinical coronary CT exams. They will also be given in the research CT exam. Beta Blockers are associated with the following risks: dizziness or lightheadedness, nausea, stomach pain, vomiting rash or itching. Nitroglycerin is associated with the following risks: low blood pressure, dizziness, headache with vision changes. A registered nurse will be administering these medications, and a physician will be available to assist you if you experience any symptoms during your research exam. Your vital signs will be monitored before and after your exam. After the exam, you will be dismissed once your vital signs return to normal.

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Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Cynthia McCollough **Phone:** (507) 284-2511 **Study Team Contact:** Research Coordinator **Phone:** (507) 538-7752 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you are having a clinically indicated coronary CT angiogram.

Why is this research study being done?

The purpose of this research trial is to determine whether images taken using a Photon Counting Detector CT scanner (PCD-CT) are better than images acquired using conventional CT scanners for the diagnosis and management of patients with suspected coronary artery disease.

Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the study. The NIH will pay the institution to cover costs related to running the study

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

Your participation in this study will end after the research CT scan has been performed.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following ways: You will be asked to sign the informed onset form before any research testing can begin. If you have the potential to become pregnant you will be asked to take a urine pregnancy test. You will be escorted to the Photon Counting Detector CT Scanner (PCD-CT) on the 3rd floor of the Mayo building by a study coordinator for your research cardiac CT exam. This scan will take approximately 30 minutes to do. Once this scan is performed, you will have completed your time in the trial.

In the rare event that something is found that might affect your health, we will notify your primary care provider. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

As with all research, there is a chance that confidentiality could be compromised; however, we take several precautions to minimize this risk.

You will be exposed to a small amount of radiation during the cardiac CT scanning. The amount of radiation you will receive has a low risk of harmful effects.

Intravenous contrast injections are associated with a small risk of kidney injury, allergic reaction, and leakage of intravenous contrast from your vein into the soft tissues of your arm. If you have had a previous allergic reaction to iodine contrast injections or have signs of decreased kidney function, you are not eligible to participate in this study.

Beta blockers to reduce your heart rate and nitroglycerin to dilate your coronary arteries are routinely given for clinical coronary CT exams. They will also be given in the research CT exam.

Beta Blockers are associated with the following risks: dizziness or lightheadedness, nausea, stomach pain, vomiting rash or itching.

Nitroglycerin is associated with the following risks: low blood pressure, dizziness, headache with vision changes.

Are there reasons you might leave this research study early?

If you experience discomfort or other symptoms during the research CT exam, you may request to stop the study. Your participation would then be complete.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

In the rare event that a finding might affect your health, we will notify your primary care provider. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. Your participation will help doctors and physicists determine if this new type of CT scanner can provide important clinical information not available using routine CT cardiac CT scanning

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- A Research CT scan with intravenous contrast.
- A urine pregnancy test (if you have the potential to become pregnant). A negative pregnancy test, which is not part of your routine clinical care, is required to participate in this study.
- The medications if used for your coronary CT scan. These drugs could include Beta Blockers or Nitroglycerin.

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

In the rare event that a finding might affect your health, we will notify your primary care provider. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will be compensated $50 for the additional time it takes to participate in this study.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address, and

Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

A two-hour parking pass will also be provided to cover your additional time on campus.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your data will be kept in a locked file cabinet, and any electronic records will be password protected.

We have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- DHHS, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and

why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews, and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions. The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the

individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

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Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature