Translational Development of Photon Counting CT-imaging
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INSTITUTE/CENTER: Clinical Center

PRINCIPAL INVESTIGATOR: Elizabeth C. Jones, MD

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Cohort: *Standard*

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WHO DO I CONTACT ABOUT THIS STUDY?

Principal Investigator:
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Study Coordinators:
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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you to in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

- This consent is for a research study and your participation is voluntary.
- You may choose not to participate for any reason and at any time.
- You are being asked to participate in this study because you are scheduled for a computed tomography (CT) scan as part of your standard care at the NIH Clinical Center.

- The purpose of this study is to test a new type of CT scanner called a photon counting CT, to see if it provides better images at a lower x-ray (radiation) dose.
- The new photon counting CT scanner used in this study is considered investigational, which means it is not approved by Food and Drug Administration (FDA).
- The photon counting CT is not needed for your medical care and is for research purposes only.
- Participating in this study will add approximately 5-10 additional minutes to the usual CT scan time but both the standard scans and the photon counting CT scan will occur on the same CT scanner.
- If you choose not to participate in this study, only the standard CT scans will be performed as ordered by your research team.
- If you choose to participate in this study, once the CT scans are complete, your study participation in this study ends.
- Collected CT imaging may be de-identified and used for future research studies or for other research questions.
- The photon counting CT scan uses x-ray radiation to make the images.
- The radiation amount for the photon counting CT scan is the same amount as for a standard CT scan. For example, if your standard scan exposed you to 2.2 rem the PCCT scan may expose you to an additional 2.2 rem for a total of 4.4 rem.
- Otherwise, the risks and discomforts with participation are the same as for a standard CT scan.
- You will not receive any benefit from participation in this research study.
- Participation in this study does not cost you anything.
- You will not receive payment for participation in this study.
- Participation in this study should not affect your future clinical care.

The remaining document will now describe more about the research study and should also be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

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WHY THIS STUDY IS BEING DONE?

This is a research study. The purpose of this research study is to test a new type of computed tomography (CT) scanner that may be used in the future. CT scans use x-rays to make three dimensional (3D) images of the body. This new type of CT scanner (photon counting CT) measures the x-rays differently than a standard scanner. We are conducting this study to see if the new scanner can provide better images at a lower x-ray dose and to compare the photon CT scan images and technique to the standard CT scan images and techniques.

We are asking you to join this research study because you are scheduled to have a standard CT scan and may be eligible to participate in this study with the new scanner.

The photon counting CT is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) for routine clinical imaging use in humans.

WHAT WILL HAPPEN DURING THE STUDY?

If we think you can be included in this study and you are willing and able to take part, you will go through pre-screening. We will review and collect information about you from your medical record. We will also review your imaging data from the past year.

If you qualify for this study after the pre-screen and decide to take part, you will be asked to:

- Provide blood and urine samples. We will need to test your blood or urine if you are a woman of child bearing age. This is to confirm you are not pregnant.
- Imaging studies done after the photon counting CT scan may be collected, analyzed and compared to the CT scans performed in this study.
- Have a CT scan. A CT scan uses x-ray radiation to make images of the body. During the test you will lie on your back on a padded table. The table will slide into a donut-shaped machine. An x-ray tube will move around your body, taking many pictures as it rotates. You will be in the CT scan machine for about 20 minutes. The CT scans requested by your healthcare team will be performed. One CT scan with the new technology will also be performed.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for approximately 20 minutes.

A standard CT scan usually takes 10-15 minutes to perform. Participating in this study adds about 5-10 minutes to your scanning time. After the CT scans are done your participation in this study is complete. There is no long-term follow-up with this study.

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HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

The study will enroll up to 750 people over 5 years with a goal of obtaining 750 photon CT scans. It is possible that some people may have more than one research scan during the 5 year study period but are not permitted to have more than 1 photon CT scan per year.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

X-ray contrast: Contrast will only be given if it is needed for your standard CT scan. The standard CT scan done at the request of your medical team are part of your medical care or your participation in an NIH research protocol.

Blood and Urine samples: We will only collect blood or urine if you are capable of becoming pregnant and have not had a test to check for pregnancy. Possible complications from drawing blood include pain, bleeding or bruising at the site, irritation of the vein, lightheadedness, fainting, and, rarely, infection. The total amount of blood drawn for this study will be approximately 1 tsp and is within the limits allowed by the Clinical Center of the National Institutes of Health.

What are the risks related to pregnancy?

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant and may be pregnant, we will perform a pregnancy test before exposing you to radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

What are the risks of radiation from research?

Radiation: The CT scanner uses x-rays to make the images. The scans done at the request of your medical team are part of your medical care *or your* participation in an NIH research protocol. The single photon counting CT scan is for research into the new CT technology. The radiation exposure from the photon counting CT is not needed for your medical care and is for research purposes only. The NIH Radiation Safety Committee reviewed the use of radiation in this research study. They approved this use as necessary to obtain the needed research information.

The average radiation dose you will receive for study of the new CT is about 2.2 rem or less, which is the same as a standard CT study. “rem” is a measure of radiation dose. For comparison, the average person in the United States receives radiation exposure of about 0.31 rem per year. This is from natural sources, such as the sun, outer space, and radioactive materials found naturally in the earth’s air and soil. The dose is below the maximum dose guidelines set by the NIH Radiation Safety Committee for research participants (5 rem). It is also below the occupational radiation dose limit (5 rem/year).

The radiation exposure described is what you will get from the additional scan only. It does not include exposure you will receive from the CT scan that is for your medical care. It does not include exposure from other tests that are a part of your medical care. If you have questions about the radiation you will receive, you should ask your doctor. If you would like more information about radiation and examples of exposure levels from other sources, please ask the investigator for a copy of the pamphlet, “An Introduction to Radiation for NIH Research

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Subjects." While there is no direct evidence that the exposure received from this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

If you are pregnant, you cannot participate in this study. It is best to avoid radiation exposure to unborn infants. They are more sensitive to radiation than adults.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Are there any potential benefits to others that might result from research?

In the future, other people might benefit from this study because it may help develop this new CT scan technology. There are potential benefits to society and future patients from this new CT scanner. These include:

- Lower x-ray dose to patients from CT scans
- Improved ability to image the body

WHAT OTHER OPTIONS ARE THERE FOR ME?

Before you decide whether to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could receive the standard CT scans requested by your health care team on one of the standard scanners in the Radiology Department. If you choose not to participate in this study, it will not affect the care you receive as a patient of the NIH Clinical Center.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

The standard CT scan requested by your healthcare providers will be stored in the Radiology Department. The study will be interpreted by an NIH Radiologist. The results will be entered into your medical record for review by your health care providers. As with any diagnostic imaging study, you may request copies of the clinical portion of your CT scan from the film library in the Radiology Department. Results from the new CT scan will not be provided to you because further research may be needed before the results are meaningful.

The investigators will not provide you with any research image results because further research may be necessary before the results are meaningful.

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EARLY WITHDRAWAL FROM THE STUDY

Your participation may end early if you cannot cooperate with the instructions for the CT scan. If you cannot lie flat on the CT table, you will not be able to participate. Your doctor may stop your participation in this study if he or she believes that is in your best interest. In this case, you will be informed of the reason.

You can stop taking part in the study at any time. If you stop participating, we will not collect any further medical information about you. According to FDA guidelines, information already collected may still be provided to Siemens Medical Solutions. If you stop participating after the CT scan is done, the scan made with the new technology may be deleted at your request. CT scans and data that have already been sent to other researchers or placed in the research databases cannot be recalled and destroyed. The scan requested by your health care team is a part of your medical record and cannot be deleted.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The Clinical Center, NIH and other government agencies, like the Food and Drug Administration (FDA) and the Office for Human Research Protections, which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- CT scans that have had your personal information removed (anonymized) may be shared with qualified representatives from Siemens Medical Solutions, the medical equipment company who manufactured the investigational CT system. The purpose for sharing this information is to provide quality assurance and aid in their further development of this new technology.

This study is protected by a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances. Please refer to the OTHER IMPORTANT INFORMATION section near the end of this consent form for more information on this type of protection.

WILL YOU SAVE MY SAMPLES OR DATA FOR USE IN OTHER RESEARCH STUDIES?

As part of this study, we are obtaining CT image data from you. We plan to use this CT image data for studies going on right now, as well as studies in the future. These studies may provide additional information that will be helpful in understanding other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners.

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There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you. By agreeing to let us use your CT image data, you give the NIH any rights you may have in the CT image data.

We will share your CT image data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or industry sponsors of research. We may also put your research data in a large database for broad sharing with the research community. These databases are commonly called data repositories. These data repositories might or might not be located at the NIH. If your individual research data is placed in one of these repositories, it will not contain information that can easily identify you and only qualified researchers will be able to look at your data. These researchers must receive prior approval from individuals or committees that monitor the use of the research information.

As part of this study, some of your information will be placed into your electronic health record maintained by the NIH. These data may be used for future research studies by NIH researchers without contacting you to ask for your permission. Because this information is part of your medical record, even if you say "NO" to the questions below on future use and sharing, we cannot always remove this information from your health record or prevent its future use for research. However, in most circumstances, any identifying information about you will be removed from your data before it is used by other researchers.

In addition to the use and sharing of your CT image data described above, we might remove any information from your CT image data that can identify you such as name, address, or medical record number, and then use the CT image data for additional research studies at the NIH or other places. If we do this, we might not contact you to ask your permission or otherwise inform you.

If now, or at any time, you change your mind and do not want us to store and use your CT image data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your samples. For example, if some research with your CT image data has already been completed, the information from that research may still be used. Also for example, if the CT image data has been shared already with other researchers, it might not be possible to withdraw the CT image data. As above, the standard CT scan obtained at the request of your health care team becomes a part of your medical record and cannot be deleted.

How Long Will My Samples and Data be Stored by the NIH?

Your CT image data may be stored by the NIH indefinitely.

Risks of Storage and Sharing of Samples and Data

When we store your CT image data, we take precautions to protect your information from others that should not have access to it. When we share your data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become

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known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your data or samples.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will I receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will I receive reimbursement or direct payment by NIH as part of my participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost me anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

There are no costs associated with participation in this study.

CONFLICT OF INTEREST

Cooperative Research and Development Agreement (CRADA)

The NIH and the research team for this study are using the photon counting CT system developed by Siemens Medical Solutions through a joint study with your study team and the company. The company also provides financial support for this study.

Siemens Medical Solutions is providing the photon counting CT system for this study to NIH through a research agreement.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. However, there are some research partners not associated with the NIH working on this study who may receive payments or benefits, limited by the rules of their workplace.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

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OTHER IMPORTANT INFORMATION

Confidentiality

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove any information that shows your identity before sharing them. You should be aware that there is a slight possibility that someone could figure out the information is about you.

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). NIH researchers must use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. NIH researchers will use the Certificate to resist any demands for information *that would* identify you, except as explained below.

There are several circumstances in which the Certificate does not provide protection. These include when information:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is necessary for your medical treatment and you have consented to this disclosure;
4. is for other research;
5. is disclosed with your consent

In addition, identifiable, sensitive information collected or compiled during research and protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent for us to disclose the research information, then the researchers will not use the Certificate to withhold that information.

The Certificate *will* not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures.

The protections of the Certificate apply to all copies of the identifiable, sensitive information collected or compiled during the research. Therefore, if an NIH investigator shares a copy of your identifiable, sensitive information with any other investigator or institution (whether a collaborator

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on this study, or researcher conducting secondary research in the future) that party must generally agree to comply with the disclosure restrictions under the Certificate described above.

Additionally, the Federal Privacy Act generally protects the confidentiality of your NIH medical records. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

Policy Regarding Research-Related Injuries

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

Problems or Questions

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Elizabeth C. Jones, M.D., ejones@CC.nih.,gov, 301-402-5606. Other researchers you may call are: Carole Webb at 301-451-9462 or Tracy Cropper at 301-402-6132. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

Consent Document

Please keep a copy of this document in case you want to read it again.

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Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process with a non-English speaking subject and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

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