Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: **Development and Translation of Generator-Produced PET Tracer for Myocardial Perfusion Imaging (Dosimetry Group)**

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

This is a research study conducted by Pamela Woodard, MD having to do with testing the safety of a new radioactive drug called ^{68}Ga-Galmydar in healthy individuals. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

HOW WILL THIS STUDY AFFECT ME?

- The purpose of this study is to evaluate a new radioactive drug called ^{68}Ga-Galmydar in healthy individuals, to test the safety and determine the distribution of the tracer in the body during PET imaging at three different imaging time sessions, immediately after injection, and repeated at 2-hours and 4-hours later. ^{68}Ga-Galmydar is investigational. This means that it has not been approved by the U.S. Food and Drug Administration (FDA).
- You were selected because you are a healthy adult over 18 years of age without cardiovascular risk factors or cardiovascular disease.

- You will be in this study for up to 14 days depending on the completion of your follow-up phone call after your imaging visit.
    - As a voluntary participant, you will be asked to spend up to about 8 hours during a visit for screening followed by the whole-body Galmydar PET imaging. This will all be done on the same day.
- You will need to come to in the Center for Clinical Imaging Research (CCIR), a Washington University facility located on the 10th floor of Barnes-Jewish Hospital.
- The main risks to you that some participants may experience are stiffness from lying still in the PET/CT scanner and discomfort from venous placement. More detail regarding risks are provided below.
- You will be paid for participating in the study. You will not receive any charges for participating in this study. You will receive $400.00 for the Galmydar PET imaging scan. If your study visits are prematurely canceled, for example, because of technical difficulties with the imaging scanner or radiotracer failure and must be rescheduled for an additional study visit, you will be reimbursed an additional $100. If you withdraw early from the study, you will be reimbursed for the portion of the study you completed. If you withdraw early from the study, the research team may continue to use information already collected about you in this study.
- This study is sponsored by the National Institutes of Health.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a healthy adult over 18 years of age without cardiovascular risk factors.

The purpose of this research study is to assess the role of ^{68}Ga-Galmydar Positron Emission Tomography/Computed Tomography (PET/CT) imaging in human subjects to improve the likelihood of understanding of the atherosclerotic disease of the heart muscle. This radiotracer may work better to image heart muscle (not heart vessels) because it looks at how well mitochondria (the "energy" center) inside the cell are working. This may help to prevent development of heart disease, heart attacks or even sudden cardiac death in individuals with cardiovascular risk.

^{68}Ga-Galmydar, a radioactive tracer, is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to come to the Center for Clinical Imaging Research (CCIR) facility, a Washington University facility, located on the 10th floor of Barnes-Jewish Hospital for your PET study for your screening and whole-body ^{68}Ga-Galmydar PET imaging scan. The screening visit will be done on the same day as your imaging visit.

The screening visit will begin in a private consultation room where the Study Coordinator will review the consent with you and go over what will happen during the study. You will have the opportunity to review the consent in private and to ask further questions before signing the consent form.

For your safety, we will ask questions about your medical history, prior surgical procedures, current medications, and family history. If you are a woman of child-bearing potential, a urine pregnancy test will be conducted. Women who are pregnant or breast-feeding will not be eligible to participate in the study. Women must avoid becoming pregnant and must agree to refrain from sexual activity or to use reliable contraceptive methods for 24 hours following administration of ^{68}Ga-Galmydar. We will also obtain a blood sample, ECG, height, weight, and vital signs.

HOW SHOULD I PREPARE FOR MY VISIT?

Prior to the Screening and PET/CT Visit:

- Leave your jewelry at home, if possible.
- Bring an updated medication list.
- Eat only a light meal 6-hours prior to your imaging visit.

On the day of your Screening and PET/CT Visit:

Screening

- If you are a woman of child-bearing potential, a urine pregnancy test must be completed and confirmed as negative prior to the PET scan.
- You can stow your personal possessions in a secure locker in the CCIR imaging facility.
- Vital sign measurements (blood pressure, breathing rate, heart rate, and body temperature) will be obtained screening, baseline within 5 to 15-min pre-injection and within 5 to 15-min -min post injection, end of first imaging session, beginning of each imaging session, and prior to discharge from the imaging facility.
- Before imaging 12-lead Electrocardiogram (ECG) lead wires will be placed on your chest to monitor your heart rhythm. A 12-lead ECG will be performed at screening, baseline within 60-min prior to injection, within 5 to 15-min post-injection, end of first imaging session, and prior to discharge from imaging facility. A total of 5 ECGs will be performed.
- You will have two catheters (IV) placed in your veins of your arms, one on the right and a second on the left. One IV will be used to inject the ^{68}Ga-Galmydar tracer and the second IV will be used to obtain blood samples.
- Safety lab testing: Blood samples will be drawn for safety testing prior to the injection of ^{68}Ga-Galmydar, shortly after the injection, and again after your PET scan is completed (approximately 2 tablespoons). You will be asked to provide a urine sample before and after the PET scan. We will compare the before and after test results to see whether or not the ^{68}Ga-Galmydar tracer made any changes your safety labs.
- Screening will take up to about 2 hours.

PET/CT Imaging

- This study will use a combined PET/CT scanner to take pictures of your body. PET scanners allow us to image the radiotracer uptake throughout your body after you are injected with a radiotracer. The CT scan (Computed Tomography) is a type of x-ray scanner that images of your body. The combined PET/CT scanner is a special type of scanner that allows us to perform whole body imaging, from the top of your head to your mid-thigh following the injection of a radiotracer.

- PET imaging will occur in three different imaging time sessions, immediately after injection for about one hour, and repeated at 2-hours and 4-hours later. You will be removed from the scanner for a break between imaging sessions.
- For your safety, your electrocardiogram (heart rhythm) and blood pressure will be monitored throughout the PET/CT exam. Research staff will be available at all times in the scanner room or in the console room. A room next to the scanner room during your imaging scan.
- PET imaging will take up to about 6 hours.

After the PET/CT Visit:

- Research staff will call you within 2-3 business days of your Galmydar PET/CT imaging scan to ask if you have any changes in your health since the scan, which should take approximately 5-10 minutes. If both days are not business days, the follow-up phone call can occur the following business day.
- You will have a second telephone follow-up phone call 5-7 days and as late as 14 days for monitoring of adverse events. Additional telephone calls may be conducted as necessary.

- The **PET/CT** images you will have for this study are for specific research purposes and are not being used to evaluate your health or find medical abnormalities. These images will not be reviewed by a radiology physician to diagnose existing abnormalities.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding disease, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your 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 Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?

We plan to enroll 38 people in this study conducted at Washington University. About 8 people will take part in the dosimetry group.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 14 days.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks stated below from being in this study. Besides these, there may be other unknown risks, or risks that we did not expect, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks associated with ^{68}Ga-Galmydar Radiotracer:

Less Likely: There are no known adverse reactions to ^{68}Ga-Galmydar. ^{68}Ga-Galmydar will be given in minimal amounts. Based on common responses to other tracers, we expect some participants may experience dysgeusia (bad taste in mouth), flushing, headache, dizziness or lightheadedness, mild gastroenteritis, pruritus, urticaria.

Rare: There is a possibility of a severe allergic reaction. Such a reaction could be serious and even cause death. Symptoms include low blood pressure, difficulty breathing, swelling of your tongue, mouth and or throat, body itching or rashes. If you experience any of these or any other symptoms, please notify the study team right away.

Risks associated with PET/CT Imaging Scanner

Likely: You may experience aching in your joints and muscles from lying still. Study staff will be nearby to stop the study in case you become uncomfortable. We will try to minimize any discomfort.

Less Likely: Some participants experience claustrophobia (anxiety because of being confined to a small space) and may experience dizziness or feel faint. The scanner will be stopped immediately if you experience these symptoms and do not wish to continue the study. Laying on the PET scanner table for a prolonged time may worsen this condition if you have pre-existing back, joint or muscle problems.

Rare: Malfunction of worn or implanted electronic medical devices.

If you have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. The CT scan may cause a malfunction of electronic medical devices.

Risks associated with Radiation Exposure

The risk associated with the amount of radiation exposure participants receive during the research study is low and comparable to other everyday risks.

^{68}Ga-Galmydar Whole-Body PET Imaging

Likely: This study will expose you to radiation from the administration of ^{68}Ga-Galmydar (galmydar labeled with gallium-68 radioactivity) and the low-dose whole-body computerized tomography (CT) scan performed during the PET scan. The maximum amount of radiation from a single administration of ^{68}Ga-Galmydar and three whole-body CT scans, when averaged over the entire body, is about 57% of the amount that a person who works with radiation is allowed to have in one year. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact sheet" at http://hrpo.wustl.edu or ask the study staff for a copy.

Risks associated with IV insertion and blood drawing

Likely: The placement of an IV (small plastic catheter tube) in your arm may be associated with a small amount of discomfort and bleeding.

Less likely: Bruising and/or bleeding at the site of the initial IV catheter placement. Occasionally some people experience dizziness or feel faint.

Rare: Infection at the site of the initial IV catheter placement.

Risks of Electrocardiogram

Likely: You may feel discomfort from the placement and removal of the electrode patches (small patches with sticky adhesive on one side that allows the patch to stick to your skin). Remaining still while the ECG is taken (less than 1 minute) may cause anxiety.

Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Radiation Exposure in Women Capable of Becoming Pregnant

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related 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.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because information from this research may improve the understanding of the atherosclerotic disease of the heart vessels, which may help to prevent development of heart disease, heart attacks or even sudden cardiac death in individuals with cardiovascular risk.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. Your check will be mailed to you approximately 3 weeks after your research visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

- $400 for the screening and whole body Galmydar PET/CT visit
- If your study visits are prematurely canceled, for example, due to technical difficulties with the imaging scanner or radiotracer failure and must be rescheduled for an additional study visit, you will be reimbursed an additional $100.
- If you complete only part of a study your reimbursement will be prorated proportionately.

WHO IS FUNDING THIS STUDY?

National Institute of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the

study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at Dr. Pamela Woodard at (314) 747-3878 or (314) 362-3386 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will make sure information cannot be linked to you (de-identified). This means that identifying information such as name or date of birth will not be included with the information and, instead, you will be referenced by a number or 'anonymous identifier'. Patient information, including anonymous identifiers used to link to research data, will be kept in a separate encrypted and password-protected database that will be accessible only to engaged team

members**.** Any documents which include patient information, including anonymous identifiers used to link to research data will be kept in a locked filing cabinet in a locked office suite; that will be accessible only to engaged team members.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.

- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue. Circumstances would include adverse reaction to administered radioactive tracers. The PI will share any new information that could change how you feel about continuing in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Pamela Woodard at (314) 747-3878 or (314) 362-3386, Dakkota Thies at (314) 747-3839, Kitty Harrison, RN at (314) 747-0183 or Molly Mohrman at (314) 747-4633. If you experience a research-related injury, please contact: Dr. Pamela Woodard at (314) 747-3878 or (314) 362-3386, Dakkota Thies at (314) 747-3839, Kitty Harrison, RN at (314) 747-0183 or Molly Mohrman at (314) 747-4633.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/24/23.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)