University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room
5018 875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Prediction of Arrhythmic Events with Positron Emission Tomography- II (PAREPET II)

Version Date: ***September 1, 2023***

Investigator: ***John M Canty, MD***

Key Information: Currently, implantable cardiac defibrillators are placed primarily on the basis of ejection fraction. However, our previous study, PAREPET I, demonstrated that nerve function, seen through a PET scan test, may be a better predictor as to whether or not a patient will actually receive a shock from their device. This study hopes to expand on our previous study and develop a series of tests to be used clinically, including PET scan, blood tests, and ECHO, to better determine who will benefit most from an ICD.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have coronary artery disease and have received an implantable cardiac defibrillator (ICD) to prevent sudden cardiac arrest (when the heart suddenly and unexpectedly stops beating).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We have previously shown that a positron emission tomography (PET) scan to measure the nerve function in the heart can predict the likelihood of developing sudden cardiac arrest. The purpose of this new study is to determine if a combination of a similar PET scan, an echocardiogram and blood tests can more accurately predict the likelihood that you will have sudden cardiac arrest or your ICD delivers therapy. Since most people who receive an ICD do not use the device, we hope that this research will improve our ability to better identify those people who are most likely to use them. The PET scan will use a radioactive drug that has been approved by the FDA for research purposes only.

How long will the research last and what will I need to do?

The initial scanning will last 2 to 3 hours. After that, you will receive a brief phone call every 3 months for up to 5 years to determine if you were hospitalized or had a shock from your ICD.

During the initial 2 to 3 hour study, you will be asked to complete a series of tests including a transthoracic echocardiogram (ECHO), six minute walk, resting ECG, and PET scan. Following the initial study, we ask that you answer a telephone call every 3 months for the duration of the study.

Is there any way being in this study could be bad for me?

The PET study involves the injection of a small amount of a radioactive imaging agent. The radiation exposure is less than that of common x-ray procedures like a CT scan. In order to limit your radiation exposure further, you will be asked to urinate immediately after the PET scan, and frequently over the next 4 hours.

An intravenous catheter will be required and this carries a small risk (less than 1 in 100) of pain, bruising, and rarely, fainting or infection. There is a small possibility that participants could experience a febrile response related to impurities in the radioactive imaging agent during its production, leg cramps and an unusual taste sensation. There is no way to predict which patients are at risk.

The Electrocardiogram (ECG) involves sticky pads which may cause some local irritation and may be uncomfortable to remove.

When collecting information from your medical records, there is a potential risk of loss of confidentiality. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. This includes limiting the identifiable information and access of the medical records to only local study personnel.

This research involves a single injection of an investigational imaging agent. While there are no known side effects of this agent and it is similar to agents that are already used to image the heart, it is possible that it could cause side effects that may be a minor inconvenience or may be more serious. While infrequent, the most common side effect of agents like this is a slight elevation in blood pressure which usually returns to normal on its own.

The procedures in this research could potentially hurt a pregnancy or fetus from radiation or unknown effects of the imaging agent. Because of this, a pregnancy test will be performed before the PET study.

There is no charge for the testing associated with this research. However, you and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, in the future we hope to limit the use of ICDs to those most likely to need the device.

What happens if I do not want to be in this research?

Your participation in this research study is voluntary. You may choose not to enroll in this study. This will not affect your regular medical care.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829-2500. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

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

How many people will be studied?

We expect about 302 people to be in this research study locally.

What happens if I say yes, I want to be in this research?

Procedures

All of the procedures for this research study will take place at the University at Buffalo's Clinical and Translation Research Center (CTRC). You will receive a copy of this consent form.

The following procedures will be done. Every effort will be made to perform them in one study visit (approximately 2-3 hours). In the rare event that they cannot be completed, an additional visit will be scheduled.

You will be asked to provide your medical history, cardiac-related symptoms and medications you are currently taking. Your hospital and office records will be reviewed to ensure study eligibility.

- Resting ECG -A research technician will apply ECG leads to your chest which will record your electrocardiogram (ECG) and heart rhythm.

- Six Minute Walk Test - this will be performed in a level, obstacle free corridor. A study nurse will supervise this and you will be asked to walk as far as you can for 6 minutes.

- Blood Sample - A member of the study team will insert an intravenous (iv) catheter and obtain a blood sample from you. We will collect about 2-3 tablespoons of blood from a vein in your arm to measure various protein levels in your body. This same catheter will be used to inject the PET tracer discussed below.

Transthoracic Echocardiogram (a sound wave or ultrasound test of your heart)- An echo technician will obtain views of the heart by moving a small instrument called a transducer to different locations on the chest. A transducer, which resembles a microphone, sends sound waves into the chest and picks up echoes that reflect off different parts of the heart.

PET (positron emission tomography) Scan - This PET scan is a non-invasive nuclear imaging test that that will measure the nerve function of your heart using a small amount of a radioactive

drug, called LMI-1195. The radioactive exposure level is low and is not considered a major risk; however, if you are of child-bearing potential, a pregnancy test will be performed before the PET scan.

A research technician will attach electrocardiogram (ECG) electrodes to your chest and a blood pressure cuff on your arm so your heart rate and blood pressure can be continuously monitored during the scan. You will be positioned on a narrow table which glides into the PET machine. After you are positioned, the radioactive drug will be given through your iv catheter and continuous scans of your heart will be recorded for up to 1 hour. You will have to lie as still as possible during the scan. You will be asked to urinate immediately after the PET scan in order to limit your radiation exposure.

Follow-up Phone Visits

After the testing, you will be contacted by phone 24-96 hours after your PET scan and every 3 months for up to 5 years to gather information about your health. During each follow-up phone call, you will be asked about any hospitalizations, or changes in heart-related symptoms or medications.

We ask that you notify us if your ICD delivers therapy (a shock or pacing) or are hospitalized at any time during the follow-up period. This will assist us in rapidly identifying the events that we would like to predict with our research. Records regarding any ICD therapies and/or hospitalizations will be reviewed.

Repeat Testing

If your ICD delivers therapy or you are hospitalized for a cardiac event, you may be asked to have these same research procedures repeated in order to determine if any changes have occurred in your condition. You are not required to have this repeat testing.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to attend the scheduled study visits.

What happens if I say yes, but I change my mind later?

You can leave the research at any time, and it will not be held against you. However, the data which has already been collected will still be included in the study database and analyses.

Is there any way being in this study could be bad for me? (Detailed Risks)

The PET study involves the injection of a small amount of a radioactive imaging agent. The radiation exposure is less than that of common x-ray procedures like a CT scan. In order to limit your radiation exposure further, you will be asked to urinate immediately after the PET scan, and frequently over the next 4 hours.

An intravenous catheter will be required and this carries a small risk (less than 1 in 100) of pain, bruising, and rarely, fainting or infection. There is a small possibility that participants could experience a febrile response related to impurities in the radioactive imaging agent during its production, leg cramps and an unusual taste sensation. There is no way to predict which patients are at risk.

The Electrocardiogram (ECG) involves sticky pads which may cause some local irritation and may be uncomfortable to remove.

Permission to Take Part in a Human Research Study

When collecting information from your medical records, there is a potential risk of loss of confidentiality. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. This includes limiting the identifiable information and access of the medical records to only local study personnel.

This research involves a single injection of an investigational imaging agent. While there are no known side effects of this agent and it is similar to agents that are already used to image the heart, it is possible that it could cause side effects that may be a minor inconvenience or may be more serious. While infrequent, the most common side effect of agents like this is a slight elevation in blood pressure which usually returns to normal on its own.

The procedures in this research could potentially hurt a pregnancy or fetus from radiation or unknown effects of the imaging agent. Because of this, a pregnancy test will be performed before the PET study.

There is no charge for the testing associated with this research. However, you and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization, the Food and Drug Administration, and the Department of Health and Human Services. The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Any personal identifiers on private information or biospecimens, such as blood samples, will be removed. After such removal, the information or blood samples may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

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.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval if we learn that all inclusion criteria are not met or an exclusion criterion is present.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institutes of Health.

Permission to Take Part in a Human Research Study

What medical costs am I responsible for paying?

You and your private or public health insurance company will not be charged for any of the tests or procedures done for this study.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call. You will get medical treatment if you are injured as a result of taking part in this study. Your study doctor will explain the treatment options to you and tell you where you can get treatment. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo, Kaleida Health, Catholic Health System, and the VA Western NY Healthcare System have no program to pay for medical care for research-related injury. By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

Will I get paid for my participation in this research?

If you agree to take part in this research study, your time and effort will be partially compensated with a personal check which you will receive after all testing is completed, to cover the expense of transportation and parking. It may take up to 6 weeks to process and receive your payments.

What are my alternatives to participating in this research study?

Your participation in this research study is voluntary. Your alternative is to not participate.

What will I be told about clinically relevant research results?

The data obtained will be used only for research and have no impact on your health care. Therefore, we will not provide our research results.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Information from your full medical records.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

- your medical history, physical exam, laboratory tests (blood and urine), medicaltesting
- information related to study visits and phone calls
- other tests or procedures that may beperformed

Permission to Take Part in a Human Research Study

- other medical information relating to your participation in this study
- your death certificate

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

__√__ KALEIDA Health, Buffalo NY

__√__ ECMC Healthcare Network, Buffalo, NY

__√__ Catholic Health System, Buffalo NY

_____ VA Western New York Healthcare System, Buffalo NY

__√__ Your primary care provider, cardiologist, and the provider of ICD follow-up

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ The sponsor of this research study, the National Institutes of Health.

__√__ The organization(s) responsible for administering this research, the Research Foundation of SUNY.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

Permission to Take Part in a Human Research Study

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual:

John M. Canty, Jr., MD
University at Buffalo
Clinical and Translational Research Center, rm 7030
875 Ellicott Street
Buffalo, New York 14203
716-829-2500

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

☐ My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PARTICIPANT NAME:	**DATE:**
PRINCIPAL INVESTIGATOR:	*John M Canty, Jr, MD*
TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the National Institute of Health about who will benefit most from Implantable Cardiac Defibrillators. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Currently, implantable cardiac defibrillators are placed primarily on the basis of ejection fraction. However, our previous study, PAREPET I, demonstrated that nerve function, seen through a PET scan test, may be a better predictor as to whether or not a patient will actually receive a shock from their device. This study hopes to expand on our previous study and develop a series of tests to be used clinically, including PET scan, blood tests, and ECHO, to better determine who will benefit most from an ICD. The initial testing for this study will last 2 to 3 hours. After that, you will receive a brief phone call every 3 months for up to 5 years to determine if you were hospitalized or had a shock from your ICD. We anticipate a total enrollment of 302 patients with around 48 patients enrolled through the VA.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You are being invited to take part in a research study because you have coronary artery disease and have received an implantable cardiac defibrillator (ICD) to prevent sudden cardiac arrest (when the heart suddenly and unexpectedly stops beating).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The PET study involves the injection of a small amount of a radioactive imaging agent. The radiation exposure is less than that of some x-ray procedures, like a whole body CT scan. In order to limit your radiation exposure further, you will be asked to urinate immediately after the PET scan, and frequently over the next 4 hours.

An intravenous catheter will be required and this carries a small risk (less than 1 in 100) of pain, bruising, and rarely, fainting or infection. There is a small possibility that participants could experience a febrile response related to impurities in the radioactive imaging agent during its production, leg cramps and an unusual taste sensation. There is no way to predict which patients are at risk.

The Electrocardiogram (ECG) involves sticky pads which may cause some local irritation and may be uncomfortable to remove.

When collecting information from your medical records, there is a potential risk of loss of confidentiality. Efforts will be made to limit the use and disclosure of your personal information, including research study

and medical records, to people who have a need to review this information. This includes limiting the identifiable information and access of the medical records to only local study personnel.

This research involves a single injection of an investigational imaging agent. While there are no known side effects of this agent and it is similar to agents that are already used to image the heart, it is possible that it could cause side effects that may be a minor inconvenience or may be more serious. While infrequent, the most common side effect of agents like this is a slight elevation in blood pressure which usually returns to normal on its own.

The procedures in this research could potentially hurt a pregnancy or fetus from radiation or unknown effects of the imaging agent. Because of this, a pregnancy test will be performed before the PET study.

There is no charge for the testing associated with this research. However, you and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. John Canty of the VA Western New York Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: (716) 829-2663

DETAILED CONSENT

WHAT IS THE PURPOSE OF THIS STUDY?

We have previously shown that a positron emission tomography (PET) scan to measure the nerve function in the heart can predict the likelihood of developing sudden cardiac arrest. The purpose of this new study is to determine if a combination of a similar PET scan, an echocardiogram and blood tests can more accurately predict the likelihood that you will have sudden cardiac arrest or your ICD delivers therapy. Since most people who receive an ICD do not use the device, we hope that this research will improve our ability to better identify those people who are most likely to use them. The PET scan will use a radioactive drug that has been approved by the FDA for research purposes

HOW LONG WILL I BE IN THE STUDY?

The initial visit will last 2 to 3 hours. After that, you will receive a brief phone call every 3 months for up to 5 years to determine if you were hospitalized or had a shock from your ICD.
During the initial 2 to 3-hour study, you will be asked to complete a series of tests including a transthoracic echocardiogram (ECHO), six-minute walk, resting ECG, and PET scan. Following the initial study, we ask that you answer a telephone call every 3 months for the duration of the study.

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*John M Canty, Jr, MD*
TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will participate in this research study at the VA Western New York Healthcare System.

Additionally, about 260 people will participate at 2 other sites across New York State, United States, and Ottawa, Canada for a total enrollment of 300 people at all sites.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

This Study will include the following:

- A call by our study coordinator to schedule testing
- Testing at the UB CTRC (Clinical Translational Research Center) next to the Buffalo General Medical Center to include:
  - Echocardiogram
  - EKG
  - 6-minute distance walk
  - Blood sample
  - An investigational imaging agent used in a PET scan of the heart
- Testing is completed in a single day and takes 2-3 hours
- Brief phone contact for follow-up every 3 months for the duration of the study
- A $60 gift card will be given as compensation after the initial 2-3-hour testing.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

All of the procedures for this research study will take place at the University at Buffalo's Clinical and Translation Research Center (CTRC). You will receive a copy of this consent form.

The following procedures will be done. Every effort will be made to perform them in one study visit (approximately 2-3 hours). In the rare event that they cannot be completed, an additional visit will be scheduled.
You will be asked to provide your medical history, cardiac-related symptoms and medications you are currently taking. Your hospital and office records will be reviewed to ensure study eligibility.

- Resting ECG - A research technician will apply ECG leads to your chest which will record your electrocardiogram (ECG) and heart rhythm.

- Six Minute Walk Test - This will be performed in a level, obstacle free corridor. A study nurse will supervise this and you will be asked to walk as far as you can for 6 minutes.

- Blood Sample - A member of the study team will insert an intravenous (iv) catheter, a flexible tube for withdrawing or introducing fluids, put under the skin or into a vein using a needle, and obtain a blood sample from you. We will collect about 2-3 tablespoons of blood from a vein in your arm to measure various protein levels in your body. This same catheter will be used to inject any contrast material for the echocardiogram if needed and the PET tracer discussed below.

- Transthoracic Echocardiogram (a sound wave or ultrasound test of your heart)- An echo technician will obtain views of the heart by moving a small instrument called a transducer to different locations on the chest. A transducer, which resembles a microphone, sends sound waves into the chest and picks up echoes that reflect off different parts of the heart.

- PET (positron emission tomography) Scan - This PET scan is a non-invasive nuclear imaging test that that will measure the nerve function of your heart using a small amount of a radioactive drug, called LMI-1195. The radioactive exposure level is low and is not considered a major risk; however, if you are of child-bearing potential, a pregnancy test will be performed before the PET scan. A research technician will attach electrocardiogram (ECG) electrodes to your chest and a blood pressure cuff on your arm so your heart rate and blood pressure can be continuously monitored during the scan. You will be positioned on a narrow table which glides into the PET machine. After you are positioned, the radioactive drug will be given through your iv catheter and continuous scans of your heart will be recorded for up to 1 hour. You will have to lie as still as possible during the scan. You will be asked to urinate immediately after the PET scan in order to limit your radiation exposure.

Follow-up Phone Visits
After the testing, you will be contacted by phone 24-96 hours after your PET scan and every 3 months for up to 5 years to gather information about your health. During each follow-up phone call, you will be asked about any hospitalizations, or changes in heart-related symptoms or medications.
We ask that you notify us if your ICD delivers therapy (a shock or pacing) or are hospitalized at any time during the follow-up period. This will assist us in rapidly identifying the events that we would like to predict with our research. Records regarding any ICD therapies and/or hospitalizations will be reviewed.

Repeat Testing
If your ICD delivers therapy or you are hospitalized for a cardiac event, you may be asked to have these same research procedures repeated in order to determine if any changes have occurred in your condition. You are not required to have this repeat testing.

Within 1 month of your initial visit, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra x-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
During blood draw, there may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood.

The PET study involves the injection of a small amount of a radioactive imaging agent. The radiation exposure is less than that of some x-ray procedures, like a whole body CT scan. In order to limit your radiation exposure further, you will be asked to urinate immediately after the PET scan, and frequently over the next 4 hours.

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VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*John M Canty, Jr, MD*
TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

An intravenous catheter will be required and this carries a small risk (less than 1 in 100) of pain, bruising, and rarely, fainting or infection. There is a small possibility that participants could experience a febrile response related to impurities in the radioactive imaging agent during its production, leg cramps and an unusual taste sensation. There is no way to predict which patients are at risk.

The Electrocardiogram (ECG) involves sticky pads which may cause some local irritation and may be uncomfortable to remove.

When collecting information from your medical records, there is a potential risk of loss of confidentiality. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. This includes limiting the identifiable information and access of the medical records to only local study personnel.

This research involves a single injection of an investigational imaging agent. While there are no known side effects of this agent and it is similar to agents that are already used to image the heart, it is possible that it could cause side effects that may be a minor inconvenience or may be more serious. While infrequent, the most common side effect of agents like this is a slight elevation in blood pressure which usually returns to normal on its own.

The procedures in this research could potentially hurt a pregnancy or fetus from radiation or unknown effects of the imaging agent. Because of this, a pregnancy test will be performed before the PET study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, in the future we hope to limit the use of ICDs to those most likely to need the device.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Subject interaction with study personnel will be limited to those necessary to complete the required testing and personal information will only be sought by the study nurse and/or PI. Patients will be placed in a private room for obtaining consent and the administration of study testing. Participants will not be placed in a common area or exposed to others in order to prevent anyone else from overhearing any conversations regarding personal information or study information.

Research Informed Consent Document

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VA Western New York Healthcare System, Buffalo, New York

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TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

All identifiable information will be stored in a locked file cabinet in a secure room and access will be limited to the PI and study coordinator. All other data will only be identified by a unique study code and access will be limited to the PI.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. The FDA may inspect study records that identify the subjects.

This study is covered by a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. You or your insurance will be billed for any standard care costs as they are not part of the study.

WILL I BE PAID FOR PARTICIPATING?

If you agree to take part in this research study, your time and effort will be partially compensated by a $60 gift card which you will receive after all testing is completed to cover the expense of transportation.

A company called “Greenphire” will manage study compensation by providing a ClinCard, which is a debit card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your ClinCard balance. The Study staff will provide you with additional information about how the ClinCard works. In order for Greenphire to be able to reimburse you using the ClinCard, Greenphire will collect the following information about you: your name (required), birth date (required), address (required), and contact details (cell phone number and/or email address – optional). By choosing to use the ClinCard service you are authorizing the release of this information to Greenphire

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA (not you or your insurance) will provide necessary medical treatment at no cost to you unless the injury is due to your non-compliance with study procedures.. If you usually pay co-payments for VA care and medications, these co-payment

requirements will continue to apply to medical care and services provided by the VA that are not part of the study.

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call. You will get medical treatment if you are injured as a result of taking part in this study. Your study doctor will explain the treatment options to you and tell you where you can get treatment. The VA Western New York Healthcare System will provide necessary medical treatment to you if you are injured by being in a research study. If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Rebeccah Young at (716) 829-2500

AFTER HOURS:

Rebeccah Young at (716) 698-0405

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this research study is voluntary. You may choose not to enroll in this study. This will not affect your regular medical care.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

The principal investigator of the study can remove you from the research study without your approval if we learn that all inclusion criteria are not met or an exclusion criterion is present.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829-2500. You may also contact the Patient Advocate at (716) 862-8752.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them if:

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

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for

Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*John M Canty, Jr, MD*
TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

overseeing the safety of human participants in this study. You may call the IRB coordinator at (716) 834-9200 Ext. 25836 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Your data will not be used for future research. The data obtained in this study will only be used for this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. James Fallavollita has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

In the future, if I decide that I no longer wish to participate in this research study, I agree that my blood specimens and data, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Participant's DOB	_____ Participant's last 4 Social Security	

_____
Name of Person Obtaining Consent

Research Informed Consent Document

Department of Veterans Affairs

VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR:	*John M Canty, Jr, MD*
TITLE OF RESEARCH STUDY:	*PAREPET II: Prediction of Arrhythmic Events with Positron Emission Tomography*

_____

Signature of Person Obtaining Consent

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.

Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date
_____	_____	_____

Indicate below your authority to act as the participant's legally authorized representative:

- ☐ Spouse
- ☐ Parent
- ☐ Adult Child (18 years of age or over) for his or her parent
- ☐ Adult Sibling (18 years of age or over)
- ☐ Grandparent
- ☐ Adult Grandchild
- ☐ Guardian appointed to make medical decisions for individuals who are incapacitated
- ☐ Other per local or state law

Specify: _____