[1341792] EXPLORER PET/CT: A Pilot Evaluation in Healthy Volunteers

PI: Lorenzo Nardo, MD PhD

Subject Screening Forms

and

Informed Consent Form

Patient Sticker on EACH Page

Subject signs in THREE places

See Notes for responses

Photocopy to Subject

Original to Binder

Medical Screening Questionnaire

For the volunteer subject: please answer yes or not to the following questions:

Item	Yes	No
1. Age ≥18 years		
2. Ability to understand and willingness to sign an informed consent form		
3. Ability to adhere to the study visit schedule and other protocol requirements		
4. Willing and able to fast for at least 6 hours before and for the duration of the scan		
5. Willing and able to lay motionless in a supine position for 60 minutes		
6. Has a primary care physician		
7. Weighing more than 240 kg		
8. Allergy to iodine contrast (only if enrolling in arm 4)		
9. Recent contrast-enhanced CT (within last 1 month)		
10. Subacute or acute infection (e.g. upper respiratory tract infection)		
11. Corticosteroid therapy in the last 48 hours		
12. Metastatic or locally invasive cancer in the last 5 years		
13. Radiation therapy in the last 3 years		
14. Chemotherapy in the last 5 years		
15. Major surgery within the last 6 months		
16. Pregnancy or breast-feeding		
17. Previous diagnosis of claustrophobia		
18. History of diabetes		
19. Blood glucose before FDG injection greater than 160 mg/dl		
20. History of kidney disease.		

Only for Arm 4. Study doctor section:

Renal function screening lab test results:

Creatinine levels > 1.5 mg/dL or estimated glomerular filtration rate (eGFR) < 60 ml/minute. Yes or No

Signature Block for study doctor:

Signature of subject	Printed name of study doctor	Date

UNIVERSITY OF CALIFORNIA, DAVIS
MEDICAL CENTER
SACRAMENTO, CALIFORNIA
PATIENT QUESTIONNAIRE
(MRI)

MAGNETIC RESONANCE IMAGING (MRI) PATIENT QUESTIONNAIRE

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant device or object.
Consult the MRI Technologist or Radiologist BEFORE. The MR system magnet is ALWAYS on.
Name: Medical Record Number:
Patient Weight:
DOB:
Date:

PATIENT QUESTIONNAIRE PRIOR TO MRI EXAMINATION

Please answer Yes (Y) or NO (N) to the following questions:

1. Do you have or have you ever had a pacemaker or implanted defibrillator? _____
   MR exams cannot be performed on patients with cardiac pacemaker and/or defibrillators. If answered Yes, the exam cannot be performed
2. Are you wearing a hearing aid? _____
3. Do you have implanted electronic devices, cochlear implants, spinal column stimulator, infusion pumps, other implants? _____
4. Have you ever had metal fragments or other foreign bodies in your eye? ____
5. Do you have any of the following in your body:
   a. Aneurysm clips? _____
   b. Heart valve prosthesis, vascular stent, or coil? _____
   c. Swan Ganz Catheter? _____
   d. IUD? _____
   e. Penile implant? _____
   f. Inferior Vena Cava Filter? _____
   g. Any other type of prosthesis? _____
6. Is there any chance that you may be pregnant? _____
7. Are you now wearing ANY transdermal medicinal patches? _____
8. Have you had ANY upper gastrointestinal study in the last two weeks? _____
9. Do you have a history of gunshot wound(s)? _____
10. Do you have any removable dentures or dental work? _____
11. Have you removed all body piercing jewelry; if any? _____
12. Do you have other metallic objects in or on your body? _____

If any of the above is “Yes” it may compromise MRI performance. Please contact MRI at 734-7959.
Signature of person completing form:

Title of research study: [*1341792] EXPLORER PET/CT: A Pilot Evaluation in Healthy Volunteers*

Investigator: *Lorenzo Nardo, MD PhD, Assistant Professor of Radiology*

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.
- If you agree to take part, you will be given a copy of this document.

Key Information about This Research Study

You are invited to participate in a research study. The purpose of this research is to test the performance of a new PET/CT scanner, which is a type of medical scanner. It is called EXPLORER and it is the first medical scanner to be able to scan the entire human body all at the same time. EXPLORER is much more efficient than previous PET/CT scanners and has the potential to make a big impact in medical care and research. You are invited to be in this study because you are a healthy volunteer who has expressed an interest in participating.

There are three different study arms for this research project. Each subject can be enrolled in only one arm; participant can choose which arm of the study he or she wants to be enrolled until the recruitment for the specific arm is complete. Your participation in this research may involve up to four visits, depending on which study arm you are in. The first visit (consenting and screening) will inform you of study details and determine your eligibility; This visit will occur at either the ACC Building Suite 3100, in the Main Hospital Nuclear Medicine Department or at EXPLORER Molecular Imaging Center (3195 Folsom Boulevard, Sacramento. During this visit you will be asked to sign an informed consent if you want to take part in the study before proceeding to the screening part. One of the study arms involves a pre-scanning visit for a blood test at UC Davis Health lab to make sure that your kidneys are working well. The other two visits involve the study scanning procedures. One day you will come for the EXPLORER PET/CT scans lasting from approximately 2 hours to 13 hours, depending on which arm you are in. The other day you will come for the MRI scanning, which will last approximately one hour. The MRI-visit needs to be completed within three weeks of the EXPLORER PET/CT visit. We expect 45 people will participate in this research at UC Davis.

Participation in this study will involve PET/CT scans and MRI scans. For the PET/CT scan, you will be injected with a small amount of a radioactive sugar (called F-18 fluorodeoxyglucose, or FDG) and you

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1341792	June 19, 2019

will lay on your back inside a long PET/CT scanner (the EXPLORER scanner). For the MRI scan, you will lay on your back on the scanner to have an MRI scan of the brain. All research studies involve some risk. These risks are described in detail later in this document. We do not expect that you will benefit from participation in this study.

Here are some reasons you may not want to participate in this research: the visit could last up to 13 hours. Avoiding strenuous exercise the day before, and fasting for 6 hours prior to the PET/CT visits, may be undesirable. For some people lying inside the scanners may cause fear or anxiety due to the confined space, and/or discomfort.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at
http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?

The person in charge of this study is Dr. Lorenzo Nardo. If you have questions or concerns about this study, please contact the Lead Researcher at 916-734-5560 or John Brock, study coordinator, at 916-734-3101.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the Nuclear Medicine Radiologist on duty. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

How is this research funded?

This research is being funded by the US National Institutes of Health (NIH) also called the sponsor. Sponsors may change or be added.

The study doctor and research staff has not received any direct income from the sponsor.

The University of California has a financial interest in this study. The University has granted a license to a private company to develop the device being tested in this study. If the device proves to be safe and effective, the University could financially benefit from the sales of the device.

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

There are three different study arms for this research project. You can decide to be enrolled in only one arm; you can choose which arm of the study you want to be enrolled in, until the recruitment for the specific arm is completed. If you decide to participate in this research study, the researchers will ask you to have up to four visits depending on which arm of the study you will be enrolled in during the initial consenting and screening visit. These are the three arms that you can choose from:

Arm 1: (15 subjects are needed for this arm)

Scanning sessions from this arm will help us to get the very best PET scans we can get from EXPLORER for clinical use, and will also give us information we need to help us to plan for a large number of different types of future research studies.

If you decide to participate in this part of the study, you will be asked to do the following:

- On your first visit (consenting and screening).
  - A member of the research team will meet you at Suite 3100 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
  - The researcher will explain in details the study: the general study design and the three specific study arms.
  - You will be asked several questions and you will be weighed in order to determine your eligibility for this study.
  - If you are eligible for enrollment, the researcher will let you know which study arms are available.
  - You will be asked to decide in which study arm you want to enroll.
  - During this visit you will be asked to sign a consent form. You can withdraw at any time by letting anybody from the research team know.

- On your second visit, you will have a series of PET/CT scans:
  - The *day before* your PET/CT scans you will need to avoid any strenuous exercise or physical labor.
  - The day of your PET/CT scans, you will need to fast (not eat anything) for 6 hours prior to your scan. Drinking plenty of water is OK.
  - You will need to avoid consuming any sugar in any form for 6 hours prior to your PET/CT scans. So, you need to avoid drinking soda or anything sweet. Drink water if you are thirsty.
  - You will also need to avoid caffeine and nicotine for six hours prior to your PET/CT scans.
  - On the day of your PET/CT scans, you will come to the EXPLORER Imaging Center at 3195, Folsom Boulevard in Sacramento.
  - Your blood sugar level will be measured with a needle-stick to make sure you do not have too high a blood sugar level for the study to work
  - You will be asked to remove your clothing and wear a hospital gown that we will provide.

- You will have an IV needle placed in a vein for an injection of 10 mCi of [18F]fluorodeoxyglucose (FDG), a radioactive sugar.
- You will then receive a PET scan on the EXPLORER scanner lasting 60 minutes after you receive the injection. This will be followed by a whole-body CT scan (quicker than 1 minute on the same scanner). Afterwards the IV line will be removed.
- You can then get off the scanner, stretch and use the rest-room
- 90 minutes after your injection, you will have another PET/CT scan. You will *not* need another injection, and the scan will last 20 minutes
- You will have another 20-minute PET/CT scan at 3, 6, 9 and 12 hours after your injection. Again, no more injections are needed, and you can get off the bed in between the scans.
- After the 3-hour PET/CT scan, you can have some snacks from a selection that we will provide.
- The total amount of time you will spend on this first visit is approximately 13 hours.

◆ On your third visit, you will have an MRI brain scan:

- The day of your MRI brain scan, you will come to Suite 0500 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
- A technologist will screen you with a survey aimed to exclude any metal or hardware in your body which may be a problem for MRI scanning
- You will be asked to remove your clothing and wear a hospital gown that we will provide.
- You will be asked to lay down on your back on the scanning table, head-first with arms at your side.
- Coils (special devices to improve image quality) may be placed around your head. The scanning table will slide your whole body into the MRI machine. During the scan you will not feel anything, but will hear intermittent humming, thumping, clicking and knocking sounds. Earplugs will be provided to help reduce the noise.
- Your MRI scan will last for about 45 minutes.

Arm *2: (15 subjects are needed for this arm)*
Scanning sessions from this arm will help us understand how we can use the efficiency of the EXPLORER scanner to reduce the radiation dose from PET scans. This is important for children who need PET scans for their care, and for future research projects where we need to scan the same subject many times.

If you decide to participate in this part of the study, you will be asked to do the following:

◆ On your first visit (consenting and screening).

- A member of the research team will meet you at Suite 3100 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
- The researcher will explain in details the study: the general study design and the three specific study arms.

- You will be asked several questions and you will be weighed in order to determine your eligibility for this study.
- If you are eligible for enrollment, the researcher will let you know which study arms are available.
- You will be asked to decide in which study arm you want to enroll
- During this visit you will be asked to sign a consent form. You can withdraw at any time by letting anybody from the research team know.

◆ On your second visit, you will have a series of PET/CT scans:

- The *day before* your PET/CT scans you will need to avoid any strenuous exercise or physical labor.
- The *day of* your PET/CT scans, you will need to fast (not eat anything) for 6 hours prior to your scan. Drinking plenty of water is OK.
- You will need to avoid consuming any sugar in any form for 6 hours prior to your PET/CT scans. So, you need to avoid drinking soda or anything sweet. Drink water if you are thirsty.
- You will also need to avoid caffeine and nicotine for six hours prior to your PET/CT scans.
- On the day of your PET/CT scans, you will come to the EXPLORER Imaging Center at 3195, Folsom Boulevard in Sacramento.
- Your blood sugar level will be measured with a needle-stick to make sure you do not have too high a blood sugar level for the study to work
- You will be asked to remove your clothing and wear a hospital gown that we will provide.
- You will have an IV needle placed in a vein for injection of 0.5 mCi of [18F]fluorodeoxyglucose (FDG), a radioactive sugar.
- You will then receive a PET scan on the EXPLORER scanner lasting for 60 minutes after you receive the injection. This will be followed by a whole-body CT scan (quicker than 1 minute on the same scanner). Afterwards the IV line will be removed.
- You can then get off the scanner, stretch and use the rest-room
- 90 minutes after your injection, you will have another PET/CT scan. You will *not* need another injection, and the scan will last 20 minutes
- You will have another 20-minute PET/CT scan at 3 hours after your injection. Again, no more injections are needed, and you can get off the bed in between the scans.
- The total amount of time you will spend on this first visit is approximately three and a half hours.

◆ On your third visit, you will have an MRI brain scan:

- The *day of* your MRI brain scan, you will come to Suite 0500 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
- A technologist will screen you with a survey aimed to exclude any metal or hardware in your body which may be a problem for MRI scanning
- You will be asked to remove your clothing and wear a hospital gown that we will provide.

- You will be asked to lay down on your back on the scanning table, head-first with arms at your side.
- Coils (special devices to improve image quality) may be placed around your head. The scanning table will slide your whole body into the MRI machine. During the scan you will not feel anything, but will hear intermittent humming, thumping, clicking and knocking sounds. Earplugs will be provided to help mask the noise.
- Your MRI will last for about 45 minutes.

Arm 3: (15 subjects are needed for this arm)

Scanning sessions from this arm will help us understand if there is any substantial difference in PET images when they are obtained using CT with contrast or without contrast (iodine contrast). This is important for planning how EXPLORER can best be used in medical care.

If you decide to participate in this part of the study, you will be asked to do the following:

◆ On your first visit (consenting and screening).
- A member of the research team will meet you at Suite 3100 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
- The researcher will explain in details the study: the general study design and the three specific study arms.
- You will be asked several questions and you will be weighed in order to determine your eligibility for this study.
- If you are eligible for enrollment, the researcher will let you know which study arms are available.
- You will be asked to decide in which study arm you want to enroll.
- During this visit you will be asked to sign a consent form. You can withdraw at any time by letting anybody from the research team know.

◆ On your second visit, we will have to test your blood to make sure that your kidneys are working well. This is critical for your safety and needs to happen within 1 month before proceeding with the scanning part of the study.
  - Your study doctor will place an order for creatinine and GFR testing (for kidney health).
  - The study coordinator will provide you with the location of the facilities where you can have your blood test (UC Davis Health lab).
  - The doctor will have access to your blood test results once they are ready. The study doctor will make the decision if you are eligible to take part of this study. In case your values are abnormal, the study doctor will discuss the results with your general practitioner physician who will guide you to possible further work up.
  - If this further screening indicates that you are still eligible to take part to this study the study coordinator will schedule the next visit (PET/CT).

◆ On your third visit, you will have a series of PET/CT scans:

- The *day before* your PET/CT scans you will need to avoid any strenuous exercise or physical labor.
- The *day of* your PET/CT scans, you will need to fast (not eat anything) for 6 hours prior to your scan. Drinking plenty of water is OK.
- You will need to avoid consuming any sugar in any form for 6 hours prior to your PET/CT scans. So, you need to avoid drinking soda or anything sweet. Drink water if you are thirsty.
- You will also need to avoid caffeine and nicotine for six hours prior to your PET/CT scans.
- On the day of your PET/CT scans, you will come to the EXPLORER Imaging Center at 3195, Folsom Boulevard in Sacramento.
- Your blood sugar level will be measured with a needle-stick to make sure you do not have too high a blood sugar level for the study to work
- You will be asked to remove your clothing and wear a hospital gown that we will provide.
- You will have an IV needle placed in a vein for injection of 10 mCi of [18F]fluorodeoxyglucose (FDG), a radioactive sugar.
- You will then receive a PET scan on the EXPLORER scanner lasting 60 minutes after you receive the injection. This will be followed by a whole-body CT scan (quicker than 1 minute on the same scanner).
- You can then get off the scanner, stretch and use the rest-room
- 90 minutes after your injection, you will have another 20-minute PET scan. This scan will be immediately preceded by 2 CTs: the first one without contrast and the second one with iodine contrast, which will be intravenously injected (through the same IV placed at the beginning of the visit). After the second CT scan, the IV line will be removed.
- The total amount of time you will spend on this second visit is approximately two hours.

◆ On your fourth visit, you will have an MRI brain scan:

- The day of your MRI brain scan, you will come to Suite 0500 of the UC Davis Ambulatory Care Center at 4860, Y Street in Sacramento.
- A technologist will screen you with a survey aimed to exclude any metal or hardware in your body which may be a problem for MRI scanning
- You will be asked to remove your clothing and wear a hospital gown that we will provide.
- You will be asked to lay down on your back on the scanning table, head-first with arms at your side.
- Coils (special devices to improve image quality) may be placed around your head. The scanning table will slide your whole body into the MRI machine. During the scan you will not feel anything, but will hear intermittent humming, thumping, clicking and knocking sounds. Earplugs will be provided to help mask the noise.
- Your MRI will last for about 45 minutes.

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is that your regular health care does not involve PET/CT or MRI scans.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study.

If you stop being in the research, data and specimens that have already been collected will not be removed from the study database.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.
- the investigators feel it is in the participant's best interest to discontinue participation. Such circumstances may include unanticipated discomfort and/or fatigue from laying on the scanner table, and feelings of claustrophobia from being inside the scanner bore.

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

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

Minor risks:

Bruising or infection at the site of the injection.

Discomfort from lying on the scanner table for up to 60 min.

Feelings of fear or anxiety related to staying in a confined space (e.g., the MRI scanner)

Radiation risks: This study involves a radiation exposure that is typical of other diagnostic tests using ionizing radiation. The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects.

There is a risk that your information could become known to someone not involved in this study.

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will record a code on the bio-specimen and information, and we will keep a link between the code and your identity in a different location.

Iodine contrast administration related risks (only for Arm 3):
Minor/Common risks:
- Bruising and/or infection at IV site
- Nausea & vomiting
- Urticaria (hives)
- Pruritis (itching)
- Diaphoresis (sweating)

Moderate/Uncommon risks
- Faintness
- Facial edema (swelling)
- Laryngeal edema (swelling of the airway in the throat)
- Bronchospasm (tightening of the airways in the chest)

Severe/Rare risks
- Pulmonary edema (fluid in the lungs)
- Respiratory arrest (loss of breathing)
- Cardiac arrest (loss of heartbeat)
- Seizures
- Death and/or permanent disabilities

What about Birth Control?

Contraception Requirements for Women

The study involves radiation that may harm a fetus or a breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you think you may be pregnant, you should not volunteer for this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study. There is no charge to you for this pregnancy test.

Will being in this study help me in any way?

Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about this new scanner.
This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. You will have to pay for basic expenses like any childcare, parking, or transportation related to study activities.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

Will I be paid or receive anything for being in this study?

We will pay you up to a maximum total of $375 for participating in this study, depending on the study arm you are allocated to. We will pay you $25 for joining the study and being injected with the radiotracer (18F-FDG, which is the most used dye in PET examinations), plus $25 for each hour you spend in the study as follows:

Study Arm	**EXPLORER Visit**	**MRI Visit**	**Blood test**	**Total**
Arm 1	Up to 13 hours	1 hour	N/A	Up to $375
Arm 2	Up to 4 hours	1 hour	N/A	Up to $150
Arm 3	Up to 2 hours	1 hour	2 hours	Up to $150

Payment will be provided at the end of the study visit in the form of gift card(s). If you choose to leave or we take you off the study before you complete the study visit, your payment will be pro-rated according to the hours spent per studies as stated in the above table (one hour = $25).
Please note that there is no compensation for the initial consenting and screening visit.

You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for participating in research, you may receive a 1099 form for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UC Davis Health, your local provider, or emergency services.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency issues, you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to nuclear medicine radiologist on-call.

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.
If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to

inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study. The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data and link between the code and your identity will be kept at the research site.

While this study does involve banking the data we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data in additional research.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
- U.S. Office for Human Research Protections
- The study sponsor, the US National Institutes of Health
- Collaborating researchers outside of UC Davis, after obtaining regulatory approvals
- Companies or groups performing services for the research team, such as Northern California PET imaging center staff

If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR) to ensure people caring for you at UC Davis Health will have the information they need about this research study when they provide care for you. Placing a copy of this consent form in the EMR is intended only to give information to caregivers providing treatment for you while you are on this study.

We will access protected health information (e.g., your medical record) for this study and you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your medical records may be looked at by the sponsor of this study and

government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Biological specimens (urine and blood sample) are used only for screening purpose. After the results are recorded the biological specimens will be discarded.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

- To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
- To meet the requirements of the U.S. FDA;
- If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
- If information about you must be disclosed to prevent serious harm to yourself or others such as child abuse, elder abuse or spousal abuse;
- If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research.

Will I receive any results from this research?

The results of this research will not be shared with you with the exception of critical findings requiring immediate or urgent intervention as defined by the department of Radiology procedure policy. In this case we will call you directly, if you agree to provide us with a phone number.
For your safety if one of the study physicians discover anything that raises suspicions of serious disease in your scans (but not requiring immediate or urgent intervention), your primary care doctor will be notified, and your doctor will decide if you need any follow-up health care. Not all abnormal findings will be reported to your primary care physician or will be followed by your primary care physician because this may lead to unwarranted risks associated with further diagnostic and/or invasive procedures. Having a primary care physician is a requirement to participate to this study. If you do not have a primary care physician, you are not eligible for enrollment.

If detected abnormal findings require primary care physician involvement, the images containing the findings will be shared with the primary care physician. Notification to your primary care physician will

occur within 2 weeks from your EXPLORER PET/CT scan and accompanied by images. In addition, we will notify you (phone call) that your primary care physician was contacted so that you can follow up with your primary care physician to establish what is the next best step to take.

If you agree with this, please provide us with the consent to share your medical data with your doctor and his/her name, address and phone number:

I agree to be directly contacted by phone in case of critical findings which requires immediate or urgent intervention:
Yes
No

I agree to share my medical information with my doctor:
Yes
No

General Practitioner information:

Physician name

Address

Phone number

Printed name of person obtaining consent

Will information or leftover specimens be used for other research?

During this research, the study team will obtain information about you. They will also collect biological specimens from you such as blood (to check your blood glucose level and renal function) or urine (pregnancy test). The information and specimens will be used for this research.

May we contact you by phone and/or e-mail?

We are requesting your phone and/or email address so we can communicate your scheduled visit with you. Phone number is generally a more direct and faster way to communicate and it will be always preferred in case there will be the need of an immediate or urgent intervention based on the results of your scans and/or tests. Email is generally not a secure way to communicate about your health, as there

are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact John Brock, Study Coordinator, 916-734-3101. You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ Yes, may use phone to contact me for this study for any clinical or research purpose. My phone number is: _____

_____ Yes, may use phone to contact me for this study only if clinically necessary (critical findings). My phone number is: _____

_____No, I do not want to be contacted by phone for any reasons

_____ Yes, may use email to contact me for this study My email address is: _____

_____ No, I do not want to be contacted by email.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1341792	June 19, 2019

Signature Block for Capable Adult

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

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

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1341792	June 19, 2019

IRB# 1341792

University of California **Davis Health**
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):

EXPLORER PET/CT: A Pilot Evaluation in Healthy Volunteers

Principal Investigator Name:

Lorenzo Nardo, MD PhD

Sponsor/Funding Agency (if funded):

NIH

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that UC Davis Health can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Davis Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☑ Entire Medical Record	☐ Lab & Pathology Reports	☐ Emergency Department Records
☐ Ambulatory Clinic Records	☐ Dental Records	☐ Financial records
☐ Progress Notes	☐ Operative Reports	☐ Imaging Reports
☐ Other Test Reports	☐ Discharge Summary	☐ History & Physical Exams
☑ Other (describe)	☐ Consultations	☐ Psychological Tests

Study billing only

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

___I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
___I agree to the release of HIV/AIDS testing information.
___I agree to the release of genetic testing information.
___I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information??

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's affiliate organization, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)--*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____

Parent or Legally Authorized Representative's Name (print) Relationship to the Subject

_____ _____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date

EXPLORER PET/CT: A Pilot Evaluation in Healthy Volunteers

URINE PREGNANCY TEST REPORT

_____

Candidate's Name

Test Result: ☐ Positive ☐ Negative

_____ _____ _____

Signature of Study Candidate Date Time

_____ _____ _____

Signature of Investigator Date Time