Total-Body Parametric ^{18}F-FDG PET of COVID-19

NCT04841707

Consent document for IRB # 1697954

Consent Version Dated 12/22/2021

Title of research study: Total-Body Parametric ^{18}F-FDG PET of COVID-19

Principal Investigators: Guobao Wang, Ph.D., Simon R. Cherry, Ph.D., Lorenzo Nardo, M.D.

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

We invite you to take part in a research study because you are of at least 18 years of age and are in the recovery phase of coronavirus disease 2019 (COVID-19). This study adds a total-body parametric ^{18}F-fluorodeoxyglucose (FDG) positron emission tomography (PET) imaging test to evaluate the response of organs to the disease.

What are my rights as a research subject?

- 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**.**

What are my rights when providing electronic consent?

- California law provides specific rights when you are asked to provide electronic consent:
  - You have the right to obtain a copy of the consent document in non-electronic format
  - You have the right to provide consent in a non-electronic format.
  - If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent, please tell the study team
- This agreement for electronic consent applies only to your consent to participate in this research study.

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 (916) 731-9004.

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 nuclear medicine physician on duty. In the case of an emergency, dial 911 from any phone.

This research has been reviewed by an Institutional Review Board (IRB). Information to help you understand research is on-line at https://research.ucdavis.edu/policiescompliance/irb-admin.You may talk to a IRB staff member at (916) 703-9158, hs-irbeducation@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- 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 have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

COVID-19 is a global pandemic with rapid spread. Our knowledge on the disease, however, is still very limited. It is also largely unknown to what extent the disease affects the lungs and other organs in individuals. There is an urgent need to develop and test new methods, especially noninvasive imaging methods, to efficiently evaluate the disease severity and monitor therapeutic response. Conventional imaging methods such as computed tomography (CT) may be used for assessing COVID-19, but mainly measure anatomical changes that commonly occur at a late stage of the disease. Using the world first total-body PET scanner (called EXPLORER), we investigate total-body dynamic PET imaging for characterization of the functional changes in the lungs and other organs (e.g., brain, heart) between COVID-19 and normal subjects. This method, if successfully validated, has the potential to enable early identification of patient with higher risk and early treatment response assessment.

How long will the research last?

We expect that you will be in this research study for about 1 year. You will be actively involved for 2 study visits, each of which will last about 120 minutes. We will follow your progress for about 1 year after the visits.

How many people will be studied?

We expect about 15 people here will be in this research study.

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

After providing your consent, we will schedule the two study visits. Depending on your medical history, we may ask you to undergo an antibody COVID-19 test (paid by the study) while we screen you for enrollment into this study. This is a blood test that will require 3.5 ml (less than 1 teaspoon) of blood to be drawn. To make sure you are no longer contagious, we will work with you to schedule a COVID-19 test (paid by the study) at least 14 days after your positive COVID-19 test. The research study will pay for this test. On the day of each visit, we will ask you to fast for 6 hours before your visit. You will be asked to arrive at the UC Davis EXPLORER Molecular Imaging Center (3195 Folsom Blvd, Sacramento,

CA). We will begin by performing a urine pregnancy test if you are a participant between 18 to 60 years old able to become pregnant, unless documented hysterectomy or bilateral ovarian removal is available. We will then be testing your blood sugar using a standard fingerstick method. After this, we will have you lie on your back inside the scanner. A dynamic positron emission tomography / computed tomography (PET/CT) scan will be performaned using a small amount of a radiolabled sugar, called ^{18}F-fluorodeoxyglucose (FDG). The scan will last for about 60 minutes.

In addition to the scan described above, we will do a 3-5 minute memory and congnition test with you. After this, your visit will be complete.

The visit described above will be repeated at 4 months from the baseline image visit. A member of the research team will reach out to you prior to the 4-month scan to inquire about the status and date of COVID-19 vaccination.

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

You may decide not to take part in the research, and it will not be held against you.

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.

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

You may have some side effects while on this study, similar to what may happen when you undergo a standard-of-care PET/CT scan.

• Minor and common clinical risks: the placement of the intravenous needle in a vein may cause temporary discomfort and a small bruise may form.

• Moderate and uncommon clinical risks: Infection at the site with the intravenous catheter is placed.

• Radiation risks: the clinical 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.

Additional potential harm from the study are the following:

• You may experience reactions ranging from feeling uncomfortable or having an anxiety reaction (ie; claustrophobia) from laying down in the scanner for 60 minutes. This feeling or reaction could occur anytime during the 60-minute scan. Please tell the study team if you have problems with being in a tight space for a long time

You should not be or become pregnant while on this research study.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. If necessary for your care, this information will be provided to you or your physicianThe sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If we access protected health information (e.g., your medical record), 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.

At the time of collection of data, your identifiable information will be entered into the system database. The PET/CT images created for this study are for research and are not meant to judge the level of your health, as they would be if they were part of your medical care. The images will not receive the usual clinical review by radiologists who interpret PET/CT scans. This means that some findings may be overlooked or misinterpreted. However, if a member of the study team, while reviewing your images, notices any findings they will share this with the Study Radiologist. If the Study Radiologist thinks a medical problem might be present, we will contact you within 8 weeks to discuss the possible medical problems or immediately if it appears urgent to the Study Radiologist. If you request it in writing, we can provide you with a copy of a section of your CT and PET images to take to a doctor you designate. We may not be able to share any images from the PET or CT portion of your scan if they are difficult to interpret or if we are restricted by the sponsor of the study. We will send a letter to a doctor you designate letting them know that you are enrolled in this study and that it included getting a PET/CT scan for research. The letter will also state that the images did not receive the usual clinical review but that findings related to a possible medical problem were seen by a UC Davis radiologist. Your doctor can contact the Study Doctor at any time to discuss your PET/CT scan.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. A possible reason to withdraw you from the study might be if the investigators feel it is in your best interest to do so.

Can I be removed from the research without my OK?

You will be paid $100 for each scanning visit you complete to compensate for transportation and other trip costs associated with your participation in this research study. This payment will be in the form of gift cards.

What else do I need to know?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by 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 call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

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	

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1697954	January 4, 2022