Informed Consent Cover Page for FDAAA consent posting:

Official Title:	Characterization of Tissue-Specific Immune Responses to Bronchoscopic Instillation of Mycobacterial Antigens into the Human Lung
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PRINCIPAL INVESTIGATOR: Ifeanyichukwu U. Anidi M.D. Ph.D.

STUDY TITLE: Characterization of Tissue-Specific Immune Responses to Bronchoscopic Instillation of Mycobacterial Antigens into the Human Lung

STUDY SITE: NIH Clinical Center (CC)

Cohort: *Healthy Adults, Confirmed latent tuberculosis infection (LTBI)*

Consent Version: 05/15/2024

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

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

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

We are studying how the cells within the lung react (immune response) when exposed to Tuberculin Purified Protein Derivative (PPD). PPD is a combination of proteins that are used to test if you have been exposed to tuberculosis (TB). PPD is a liquid that is commonly injected under the skin. We plan on applying this into one of the small airways of your lung. We want to learn if lungs of subjects who have not been previously exposed to TB, healthy volunteer no latent tuberculosis infection (non-LTBI), react differently from the lungs of subjects who have been exposed to TB confirmed latent tuberculosis infection (confirmed LTBI). We will determine if you have previously been exposed to TB by confirming if you have positive results to a skin test and blood test which indicate TB exposure. The study will not put you at risk of contracting TB since at no point or time will TB bacteria be used in this clinical trial.

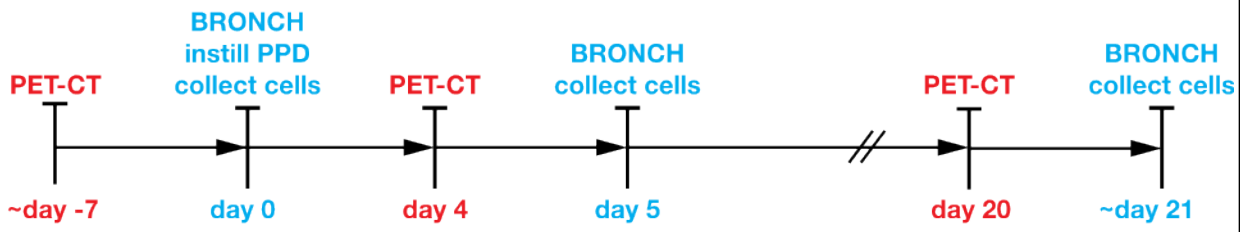
To study how the cells react in the lung we need to instill (apply/spray) PPD into a small section of your lung using a bronchoscope. We will measure the immune response by taking a sample of the cells in your lung and blood, and use a chest FDG PET-CT scan to measure the response in your chest lymph nodes. To understand this better we need to collect lung cells with a bronchoscope, collect blood cells with a blood draw and image your chest lymph nodes with a PET-CT scanner at three separate times.

We are asking you to join this research study because you have been deemed eligible based on the screening tests completed that are listed below under “what will happen during this study”. We are looking at two groups **1) Confirmed LTBI PPD positive and Interferon Gamma**

Release Assay (IGRA) positive and **2) Healthy volunteer PPD negative and IGRA negative non-LTBI.**

You will be asked to come to the NIH no more than 8 times, 10 times if rescreened, and will remain in the study for up to 30 days. You will be asked to return to the NIH for 3 FDG PET CT scans and return additional days for 3 bronchoscopies.

First you will be asked to have a baseline chest FDG PET-CT scan. Approximately 7 days after the FDG PET CT scan, the PPD solution will be applied into a small section of your lung using a bronchoscope. You will need to return 4 days later to have a repeat chest FDG PET-CT scan. After the second FDG PET-CT scan you will need to return the next day for collection of lung cells with bronchoalveolar lavage (BAL) using a bronchoscope and blood cells with a blood draw. About 3 weeks later you will be asked to return and receive the final FDG PET-CT scan, and you will need to return the day after for the last collection of lung cells using the bronchoscope with BAL and blood cells with a blood draw. See the timeline below:



No adverse events have been reported in similar studies following the instillation of PPD using bronchoscopy. The general risks associated with this study pertain to the following: Bronchoscopy, PET-CT scan, blood draw, and EKG. These are described further in this consent.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

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

WHY IS THIS STUDY BEING DONE?

This is a research study. We are studying how the cells within the lung react (immune response) when exposed to PPD. Understanding how the cells and the lung react may be important in the development of TB vaccines, diagnostics, and directed therapies.

To do this we plan to study healthy adults 18- 64 years old to compare the immune response in the lung, blood cells, and chest lymph nodes using FDG PET CT scan after PPD is instilled into one of the small airways of your lungs.

Two groups: 1) Healthy confirmed-LTBI PPD positive and IGRA positive 2) Healthy non-LTBI PPD negative and IGRA negative.

Healthy confirmed-LTBI means you have been exposed to tuberculosis TB, but do not have active disease or symptoms. Healthy non-LTBI means you have not been exposed to TB according to the skin and blood test you completed at the screening visits.

We are asking you to join this research study because you are either a healthy adult without TB exposure or you have been exposed to TB in the past (healthy confirmed-LTBI) without active disease, and agree to adhere to the study regimen from screening until day 21 including a telephone follow-up visit on day 30. Both groups will undergo the same study procedures. You may be eligible to be rescreened to participate at a later date if at the time of enrollment the baseline visit is not completed within 60 days after the screening tests are completed, or you are found to have an active infection, recent vaccination, and or have been exposed to radiation within the last 12 months of $\geq$2.3 rem. The study team may contact you at a later date and you can decide if you would like to continue your participation and complete the screening again.

NIH staff member study participation. If you are an NIH staff member, we will give you an extra information sheet. In light of that information, please raise any concerns you may have with the study team.

Application of Tuberculin Purified Protein Derivative (PPD) into the lungs with a bronchoscope is considered investigational. This means that though it has been approved by the U.S. Food and Drug Administration (FDA) for administration under the skin, it has not been approved for administration with a bronchoscope.

However, the use of Tuberculin Purified Protein is approved to the diagnosis of latent tuberculosis infection. We are testing it in this research study to determine the localized immune cell response in the lung after directed bronchoscopic instillation.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to:

Screening Visit 1 & Visit 2 (can be done 60 days before you start study visits)

If rescreened after 60 days the TST, IGRA, & chest x-ray will not be repeated unless there is a known tuberculosis exposure.

- Current and past medical history.
- Pregnancy test if applicable, and current breast feeding status
- Blood tests
    - to check for lung infection, viral infection including HIV, kidney, liver disease, or a blood disorder, and TB blood test Interferon- Release Assay (IGRA) also called QuantiFERON Gold Test
- EKG

- Tuberculosis Skin Test (TST). A second TST may be completed 1 to 3 weeks after the first test (two-step) if the study team needs to confirm the test results are negative.
- PCR COVID-19 test
- Chest X-ray

We will arrange for you to come back for your results no more than 3 days later. If you have active TB (identified by your chest x-ray and PPD or IGRA results) we will direct you to where you can receive treatment. If we confirm that you have latent TB infection, we will also recommend evaluation and possible treatment with your primary care provider or your local county health department.

Baseline test if you are eligible based on the screening tests.

- Physical exam including current and past medical history. Height weight, vital signs, temperature, O_2 saturation
- Blood tests (to check for infection, kidney, liver disease, or a blood clotting disorder)
- Pregnancy test if applicable
- FDG PET/CT

Study Day 0 (about 7 days after Baseline testing)

- Pregnancy test if applicable
- Research blood collection 40 mL about 2.5 tablespoons
- EKG
- Bronchoscopy. Medications given to relax you midazolam and fentanyl. Study drug PPD.
- Adverse Event Diary

Study Day 4-5

- Blood tests (to check for infection, kidney, liver disease, or a blood clotting disorder)
- Pregnancy test if applicable
- #2 FDG PET/CT
- Adverse Event Diary

Study Day 5-6

- Pregnancy test if applicable
- Research blood collection 40 mL about 2.5 tablespoons
- EKG
- #2 Bronchoscopy. Medications given to relax you midazolam and fentanyl.
- Adverse Event Diary

Study Day 20-21

- Blood tests (to check for infection, kidney, liver disease, or a blood clotting disorder)
- Pregnancy test if applicable
- #3 FDG PET/CT
- Adverse Event Diary

Study Day 21-22

- Blood test Interferon- Release Assay (IGRA)

- Pregnancy test if applicable
- Research blood collection 40 mL about 2.5 tablespoons
- EKG
- #3 Bronchoscopy. Medications given to relax you midazolam and fentanyl.
- Adverse Event Diary

Study Day 30

- Telephone follow-up call

Study Procedures:

All study procedures will be performed at the NIH Clinical Center on an outpatient basis. No hospitalization is required.

Bronchoscopy, PPD to Collect Cells : You will be asked not to eat or drink anything for six hours prior to the procedure to assure that food will not be inhaled into the lungs if you were to vomit. Your mouth and nasal airways will be numbed with topical anesthesia. We will give you medicine to relax you during the procedure called midazolam and fentanyl. With the use of midazolam there is a minor risk of vomiting and decreased respiratory rate. With the use of fentanyl there is a minor risk of abdominal pain, constipation, nausea and vomiting. The doctor performing the procedure will decide to pass the bronchoscope (a long flexible tube) though your nose or mouth into the airways of the lung. The airways themselves will be numbed with medication and PPD will be instilled into your right upper lobe of your lung. While we are in the lungs, we will perform a procedure called bronchoalveolar lavage (BAL) to collect the cells to examine in the lab. We do this by injecting a small amount of salt water and then suctioning it back out. The procedure takes 20 – 40 minutes to perform. During the procedure and immediately afterwards we may give you additional oxygen by a facemask. After the procedure, we will monitor your vital signs for 1 to 2 hours. You'll be able to go home once you're fully awake after the procedure but someone else must drive you home.

Chest FDG PET-CT scan: You will be asked to fast for 6 hours before the FDG PET-CT scan The PET scanner is a doughnut-shaped machine that uses x-rays combined with a dose of a radioactive substance (tracer) called ^{18}FDG to create computer pictures showing the inside of your body.

Before the scan, you will have a radioactive substance injected into your arm after which, you will need to wait for approximately 30 minutes for the substance to be absorbed. After 30 minutes, you'll lie on a narrow, padded table and be positioned for the scan. The scan itself is painless and won't make much noise. During this time, you will need to lie very still. It will take about another 30 minutes to complete.

Blood: We will take a total of 8 tablespoons (120 mL) of blood from a vein in your arm to use for research testing of blood cells and other clinical tests. We will collect 40 mL (2.5 tablespoons) of Research blood on study day's 0, day's 5-6, and day's 21-22.

Electrocardiogram: An electrocardiogram (EKG) evaluates the electrical activity of the heart. You will have 12 patches (electrodes) placed on your chest. The patches are connected to cables that will transmit the information from your heart to a machine.

HIV TESTING: As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will not be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for approximately 30 days: This study includes multiple Out-Patient visits, and a telephone follow-up call on day 30.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to screen 100 subjects in order to include 25 subjects to participate in the study tests at the NIH.

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

Bronchoscopy, to Collect Cells – Risk/Discomforts:

The bronchoscopy is not typically painful, but it may cause throat numbness, cough, a sore throat and fever. Sometimes, the bronchoscopy can cause your blood oxygen levels to temporarily fall. We will monitor your oxygen levels throughout the entire procedure and afterwards until you are recovered. The numbing spray may make your mouth feel funny and has an unpleasant taste. Common side effects of the drug administered through the IV include feeling dizzy, faint, lightheaded, tired or out of breath. You will be watched closely throughout the procedure, and we will treat any side effects that occur.

In addition to the risks of the bronchoscopy, sometimes you may have a slight fever after the bronchoscopy with BAL. This usually goes away in a day. If it persists, you should contact the study team or your doctor.

Conscious sedation medications (midazolam and fentanyl) will be given to you so you can relax during the procedure. With the use of midazolam there is minor risk of vomiting and decreased respiratory rate. With the use of fentanyl there is a minor risk of abdominal pain, constipation, nausea and vomiting.

Study drug PPD applied into the lung in previous research studies reported no serious or unexpected side effects.

FDG PET CT Scan and Chest X-Ray Risk/Discomforts:

- Radiation: You will be exposed to radiation from the Chest X-Ray and the F18 FDG PET/CT scans. You will receive up to one Chest X-ray and three F18 FDG PET CT scans. This radiation exposure is not required for your medical care and is for research purposes only. More information on radiation risk can be found below under, "*What are the risks of radiation from being in the study?".*
- Allergy Risk: There is a risk of allergic or other adverse type reaction to PET-CT radiotracers. This is extremely rare. Fluorodeoxyglucose (FDG) is a natural sugar that is attached to the radiotracer. There have not been any allergic reactions reported to FDG alone in the past. However, if a patient were to develop an allergic reaction, treatment

would be initiated immediately with diphenhydramine, ranitidine, and/or corticosteroids depending on the severity of the reaction.

- **Risk of Incidental Findings**: Unanticipated clinically insignificant or potentially significant abnormalities may be detected from the results of the PET-CT scans performed. An example of an unanticipated finding would be a nodule, or an abnormality seen on the imaging studies. This information may be considered relevant to your health care and we will provide it to you and/or your primary physician. Such abnormalities due incur the risk of future potentially unnecessary additional diagnostic testing or therapeutic intervention, which can be associated with various complications and costs. You will be responsible for following up with your primary care physician. We do not plan on providing follow-up care if this occurs.

Blood collection - Risk/Discomforts:

You may feel some pain at the needle entry site. There is a slight risk of bleeding around the site. This is not dangerous, but it could cause a bruise. Some people feel lightheaded or dizzy after have blood drawn. To reduce your risk of falling, we will monitor you closely and ask you about these symptoms before we allow you to stand up.

Electrocardiogram (EKG) Risk/Discomforts: There is no pain or risk associated with having an EKG other than the discomfort of having the electrodes attached to your chest.

What are the risks related to pregnancy?

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

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during your participation in this study, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

What are the risks of radiation from being in the study?

During your participation in this research study, you will be exposed to radiation from one Chest X-ray and three PET/CT scans each year. The amount of radiation exposure from these procedures is equal to approximately 2.71 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure

of 0.3 rem per year from these sources. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The Chest X-ray, and the Chest PET/CTs that you get in this study will expose you to the roughly the same amount of radiation as *"9 years' worth"* of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

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

This is a voluntary study to investigate the function of lung cells and the immune response when exposed to PPD. In the future, other people might benefit from providing important data relevant to the development of TB vaccines, diagnostics, and directed therapies.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Alternatives to participation in this study are to not participate or engage in this study.

DISCUSSION OF FINDINGS

New information about the study

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

Return of research results

The results of this research study will be shared with you if you make the request in writing to the study team.

Unanticipated medical finding: During the course of this study, it is possible that we will obtain unanticipated finding about your health during the imaging studies. An example of an unanticipated finding would be a nodule, abnormality, or cancer in lungs, or other areas of your body seen on the imaging studies. This information may be considered relevant to your health care and we will provide it to you and/or your referring physician. These findings may require clinical testing as a follow up to define the abnormality.

We will tell you about our research results if you wish to have that information. However, it may not be available for many years. We will not share the published results of this study with you unless you contact us.

By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Anidi.

EARLY WITHDRAWAL FROM THE STUDY

If you develop an infection while you are on the study, please contact Dr. Anidi at Phone 301-761-7811: or E-mail: Ifeanyichukwu.anidi@nih.gov.
Also, your research participation may end early if:

- Staying in the study would be harmful.
- You are not able to complete study procedures.
- You fail to follow instructions.
- You use anticoagulant therapy including platelet inhibitors (e.g. clopidogrel) within 7 days prior to the bronchoscopy or systemic anticoagulants (e.g. warfarin, enoxaparin) within 14 days prior to the bronchoscopy.
- You become pregnant.
- You are exposed to radiation during/in-between the study visits of ≥2.3 rem.
- You test positive for COVID-19.
- There may be other reasons to take you out of the study that we do not know at this time.

The Principal Investigator of this study (Dr. Anidi or the National Heart, Lung, and Blood Institute (NHLBI) Institutional Review Board (IRB) may stop this study at any time, for any reason, without your consent.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding tuberculosis infection, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely or until they are not believed to have scientific value.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

Visits to NIH	**Amount**
Screening Visit #1- 1hr	$80
Screening Visit #2- 1hr	$80
On Study Visit #1 (Baseline) – 3hrs	$120
On Study Visit #2 (Day 0)– 5hrs	$120
On-Study Visit #3 (Day 4-5)- 4hrs	$120
On-Study Visit #4 (Day 5-6)– 5hrs	$120
On-Study Visit #5 (Day 20-21) – 4hrs	$120
On-Study Visit #6 (Day 21-22)– 5hrs	$120
Total for Visits	**$880**
Procedures	**Amount**
Tuberculin skin test (TST) - $50 x 2 2nd test may not be needed	$100
History and Physical	$20
EKG - $20 x 4	$80
Blood work – $30 x 4	$120
Research blood work - $30 x 3	$90
Screening Chest X-ray	$20
PET-CT - $250 x 3	$750
Radioactive tracer - $80 x 3	$240
Bronchoscopy - $300 x 3	$900
PPD Study drug given with 1st Bronchoscopy	$50
Fentanyl and Midazolam IV admin - $20 x 3	$60
Escort fee for person staying with vol after bronch $20 x3	$60
Total for Procedures	$2,490
Total (Visits and Procedures) - $880 +2,490	$3,370

If you are unable to finish the study, you will receive financial compensation for the parts you completed. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

This study does not offer reimbursement for parents and participants, or payment of, hotel, travel, or meals.

Reimbursement will be provided if traveling by train or bus for long distance travel which is greater than 50 miles away from the NIH, or car mileage will be reimbursed at 0.40 cents per mile if traveling more than 30 miles away from the NIH.

COSTS

Will taking part in this research study cost you anything?

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

There are no costs associated with your participation in this study.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.
No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

While we can do some of our tests immediately, we may store your samples in the freezer for future use. In addition, we will store certain information in your medical record. We may be interested in using your samples to pursue other research. We may send your samples elsewhere for analysis. If we do so, we will not reveal your identity, but there will be a code to link your samples with your name and other personal information. The code will be stored in a password protected database under the control of Dr. Anidi . We will use this information to do scientific research, publication, and teaching. If we share or publish these data and images, we will remove your name and personal identifiable information from data and medical images, to ensure that there is no way for you to be identified from this information.

Because you will receive compensation to cover time and inconvenience for some of research tests done for this study, we will need to collect your Social Security Number, if you have one, in order to process payment. This number will be kept safe in your medical record. If you prefer not to provide that number to us, you may not be able to receive compensation for your participation in

this study. However, if you do not have a Social Security Number, you may be asked to give your passport number, we may be able to issue you a check.

Will your medical information be kept private?

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

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

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

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

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or

2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

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

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Ifeanyichukwu Anidi, M.D., PhD, Ifeanyichukwu.anidi@nih.gov, at 301-761-7811. Other researchers you may call are: Kevin Fennelly, MD, MPH, kevin.fennelly.nih.gov, 301-385-0807. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

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

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Signature of Witness*	Print Name of Witness	Date

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

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

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