Brain Imaging in Tobacco Smokers During a Quit Attempt

NCT04055467

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If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Brain imaging of nicotinic acetylcholine receptors in tobacco users and nonusers**

Application No.: **IRB00173536**

Sponsor: **National Institutes of Health**

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information)

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to examine whether the brains of people who smoke cigarettes are different from the brains of non-smokers. Healthy volunteers who smoke cigarettes may join. You should not participate in this study if you are already actively attempting to quit smoking and you should not delay seeking treatment to help you quit smoking so that you can participate in this study. Those who are interested in participating will first complete a 3-hour screening visit. In addition to the screening visit, eligible smokers who join the study will complete a baseline visit with an MRI scan when smoking as usual, followed by a practice quit attempt, and PET scan. For the practice quit attempt you will try to not smoke for at least 1 day and try to continue abstinence for 8 days. During this time, you will come to the lab for 2 visits where you provide breath and urine samples which will tell us whether you have stopped smoking and you will also complete questionnaires which ask about your mood and other tasks testing your cognitive performance. You can receive incentive payments if you provide breath and urine samples that show you are successfully abstaining from smoking cigarettes during your quit attempt

visits. If you complete the PET scan, you will be asked to complete the third visit even if you are unable to stop smoking for the full 8 days of the quit attempt, and are eligible for the completion bonus. All study procedures will typically be completed in 2-4 weeks.

The MRI exam in this study take about 60 minutes. Being inside the MRI machine can make some people feel confined (claustrophobic). If this bothers you, please tell the MRI staff. The MRI machine uses a strong magnet to take pictures of your brain but it can also attract other metals. You may not take part in this study if you have a pacemaker, an implanted defibrillator, or certain other implanted electronic or metallic devices, shrapnel, or other metal.

For the PET scan, you will have 2 catheters (plastic tubes) placed. One will be inserted into a vein in one of your arms (intravenous line or 'IV' line) and the other into an artery in the wrist of your other arm (arterial catheter) by an anesthesiologist or other qualified medical staff member. The anesthesiologist will use a drug named Lidocaine to numb the area on your wrist where the arterial line will be inserted. The catheters allow us to easily inject liquids into you and remove blood samples. PET scan procedures require the placement of these catheters. If we cannot successfully insert both catheters, then the PET scan will be cancelled. The research staff may or may not reschedule your PET scan. During the scan, we will give you a drug called ^{18}F-ASEM through the catheter placed in your forearm vein, which will allow us to see chemical activity in the brain. We will withdraw a small amount of blood during the PET scan from the arterial catheter. The total amount of time required for the PET scan is about 4 hours but you will only be in the scanner for about 90 minutes. Four hours is required to prepare you for the PET scan and to remove the catheters and monitor you after the PET scan.

There is no cost for participating in this study, other than traveling to and from the research location and you will not receive any direct benefits from your participation.

2. Why is this research being done?

This research is being done to learn more about neurological differences in the brains of people who do or do not smoke cigarettes. These results will help us understand how the brain can change as a result of smoking cigarettes.

Are there any investigational drugs/devices/procedures?

During the PET scan, you will be given a radiotracer called ^{18}F-ASEM in order to allow us to see chemical activity in your brain. The use of ^{18}F-ASEM in this study is investigational. The word "investigational" means this ^{18}F-ASEM is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies. The FDA is allowing the use of ^{18}F-ASEM in this study.

Who can join this study?

Healthy volunteers who smoke cigarettes may join the study.

How many people will be in this study?

We expect 18 people to complete this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- You will be asked to wear a properly fitting surgical grade face mask to reduce COVID-19 transmission risk while in the research facilities and interacting with study staff. We will provide one

to you at no cost. **You must wear a mask as directed to participate in the study.**

Screening Phase

You will be asked to answer some questions and complete some tests to see if you are eligible to take part in this study. This is called "screening" and will take about 3 hours to complete. Some screening can be completed on the phone or by completing questionnaires online. Some parts of screening require in-person visits. During the screening visit:

- You will be asked to tell us about yourself (for example, your full name and date of birth) and to answer questions about your medical history and past use of legal and illegal drugs.
- You will be asked you about your alcohol use, drug use, cigarette smoking, mood, feelings, stress levels, medical and psychiatric problems.
- We will measure your weight, blood pressure, heart rate, and will conduct a routine medical history and physical examination that will be used to determine if you are healthy enough to be in the study.
- A small amount of blood (about 2 teaspoons) will be taken for routine laboratory tests to check your blood counts, liver and kidney function.
- You will be asked to provide breath samples to test for recent drinking and smoking.
- You will be asked to provide a urine sample to test for cigarette use, and use of other drugs and a urine pregnancy test for women capable of having children. A negative pregnancy test is required for all women capable of having children. A positive drug test for anything aside from cigarettes at any point during the study will result in cancellation of the visit. The research staff may or may not reschedule your screening for a positive alcohol or drug screen.
- We will also obtain an electrocardiogram (ECG), which is a measure of how healthy your heart is. The ECG measures the electrical activity of your heart, and involves putting small sticky electrodes, like Band-Aids®, on your chest. Sometimes these sticky electrodes are also put on your arms and legs.
- If you have been treated at Johns Hopkins, we will review your medical records to see if there are any medical concerns that would make it dangerous for you to be in the study.

This screening visit will help us determine if you are eligible to continue the study. If you are not eligible for this study, your study participation will end after the screening visit.

Study Visits

If you are eligible, you will be asked to complete visits at the Johns Hopkins Bayview Medical Center (JHBMC) and the Johns Hopkins Hospital (JHH) with the following procedures:

MRI Scan:

Magnetic Resonance Imaging (MRI) scans create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRI exam. Most MRIs take about 60 minutes. This visit is completed before the practice quit attempt as part of your 'smoking as usual' visit.

You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal. If you have a history of metal in your head or eyes, you will need an x-ray exam of your skull in order to find out if the MRI exam is safe for you.

The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam. While no significant risks have been found from the use of MRI scans, you may be bothered by the noise made by the MRI scanner and by feelings of being closed in (claustrophobia). You will not be able to participate in any study procedures, including the MRI scan, if you are pregnant.

Incidental findings
As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. <u>You do not have an option to decline information about an incidental finding from an imaging procedure.</u>

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?
- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company's responsibility.

PET Scan
You will participate in one PET scan at the JHH PET Center. A urine sample will be collected for a pregnancy test (for females) and a drug test. You will complete several self-report measures on your recent lifestyle and behaviors and current mood.
To be eligible to complete the PET scan, you must be able to abstain from smoking for 1 day.

To prepare for the PET scan, you will have 2 catheters (plastic tubes) placed. One will be inserted into a vein in one of your arms (intravenous line or 'IV' line) and the other into an artery in the wrist of your other arm (arterial catheter) by an anesthesiologist or other qualified medical staff member. The anesthesiologist will use a drug named Lidocaine to numb the area on your wrist where the arterial line will be inserted. The catheters allow us to easily inject liquids into you and remove blood samples. PET scan procedures require the placement of these catheters. If we cannot successfully insert both catheters, then the PET scan will be cancelled. The research staff may or may not reschedule your PET scan.

Women will have a small amount of blood drawn using the IV line; we will use this blood to measure a hormone to determine what menstrual phase you are in.

Before the scan, a thermoplastic facemask will be constructed. It will take about 10 minutes to make the facemask. To make the mask, a soft, warm piece of plastic will be laid across your face. The plastic touches your face from your forehead to the middle of your nose. The plastic molds to the shape of your face and hardens as it cools.

During the scan, you will lay in the scanner in a comfortable position wearing the facemask. We will give you the investigational drug ^{18}F-ASEM that allows us to see chemical activity in the brain.

^{18}F-ASEM is given to allow us to take pictures of your brain. ^{18}F-ASEM will be given through the catheter placed in the vein of one of your arms.

We will withdraw a small amount of blood during the PET scan from the arterial catheter. Pictures will be made of your brain while you rest quietly on the scanner table. The PET scan lasts about 90 minutes. We will ask you questions about how you feel.

At the end of the PET scan, the catheters will be removed. A special bandage called a pressure dressing will be placed over the site where the catheter in your wrist was. You will be monitored in the PET Center for about 1 hour after the scan is over to make sure that you are feeling well and that there is no bleeding from the arterial line site.

You must keep the pressure dressing that was placed on your wrist clean and dry. You must avoid strenuous physical activity for 72 hours after the completion of the study. The total amount of time required will be about 4 hours. This much time is required to prepare you for the PET scan and to remove the catheters and monitor you after the PET scan.

A number of safety tests will also be performed to monitor your general condition during the PET imaging session. The study personnel will measure your pulse, temperature, heart rate, and blood pressure. They will also perform an ECG before, during and after the PET scan.

When you are discharged from the PET center, you will be provided with a telephone number you can call anytime after the study if you need assistance for problems related to the study procedures.

8-day Practice Quit Smoking Attempt

Cigarette smokers participating in this study will attempt to quit smoking for at least 1 day and up to 8-days. You will come to the lab on 2 of the 8 days of your practice quit attempt and provide urine samples, complete a breath test, and answer questions about your mood and cravings for cigarettes. During these visits, you will be paid for your time and will receive bonus payments for providing breath and urine samples that show you are successfully abstaining from smoking cigarettes. If these tests show that you are not successfully abstaining from smoking cigarettes, you will not receive the bonus payment for that day. To be eligible to complete the PET scan, you must be able to abstain from smoking for 1 day and have completed the smoking as usual visit with the MRI scan.

Will research test results be shared with you?

It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

How long will you be in the study?
If you join the study, you will complete an 8-day practice quit smoking attempt, MRI, and PET scan in addition to the screening visit. All study procedures will typically be completed in 2-4 weeks, depending on scheduling.

We ask that you keep your study appointments. If you cannot keep an appointment, contact research staff to reschedule as soon as you know that you will miss the appointment

Restrictions
Please let us know if you plan to take any new over-the-counter or prescription medication or change the dose of any medication that you already take while you are in the study. You will also be asked not to use any illegal drugs, including cannabis, until you have completed all study visits. If your urine drug test is positive for any drug when you arrive at JHBMC for your study visit, you will no longer be allowed to take part in this study.

4. What happens to data and biospecimens that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?
Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes blood, urine, and breath testing to evaluate use of cigarettes, drugs, and/or to test for pregnancy (in female participants). We also will use the blood samples collected during the PET scan to help us understand your brain chemistry.

The biospecimens you provide for this research study will be processed and then immediately discarded. Your samples will be used as part of this research study only and will not be used or distributed for future research.

How will your data be shared now and in the future?
Sharing data is part of research and may increase what we can learn from this study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:
- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Research data including your brain scans may be shared with research collaborators at Washington University in St. Louis. This information will be shared using a secure data sharing system called the Central Neuroimaging Data Archive. All data will be transferred without information that might identify you (things like your name, address, or date of birth will not be shared).

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data, we limit the uses of the information and whether these data can be shared with another research team. If data are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

This study involves several separate procedures, each of which involve some risk of discomfort:

COVID-19

During screening and all study procedures specific safety procedure are in place to minimize person-to-person contact in due to risk of exposure to the COVID-19 virus. We are doing everything we can to reduce this risk. Prior to coming to our facility for your visits, we will ask you questions about how you are feeling and whether you have had recent exposure to anyone who is COVID-positive. We may reschedule your visit. ***If you do not feel well, please call to re-schedule your visit.***

While you are at Johns Hopkins for study visits, we will require that you wear a clean surgical face mask that covers your mouth and nose at all times except when you are alone in the test rooms with the door closed to provide breath samples. These rooms have strong airflow systems used in our smoking research to circulate air. We will provide the face mask for you to use. Study staff will also be wearing face masks at all times. We will maintain social distancing during each visit to the extent possible, but there will be times such as during blood draws, when this will not be possible. During times when staff must get closer than 6ft to you, they will wear additional protective equipment such as face shields and surgical gloves.

All equipment and surfaces will be wiped down with disinfectant prior to you entering test rooms, and hand sanitizer is available.

Nicotine/Tobacco withdrawal

You may feel discomfort when you stop smoking cigarettes. This may include increases in symptoms such as anxiety, irritability, craving, sweating, and difficulty concentrating. These symptoms are not medically dangerous and typically resolve on their own within a few weeks.

MRI

While no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia).

Arterial and Venous Catheters:
You may feel a small amount of pain from placement of the IV line. There is a slight risk of bleeding, bruising, or irritation whenever blood is drawn or IV lines are started. In addition, IV fluid can occasionally escape under the skin, causing pain and swelling for a few days. When any intravenous product is given, there is always a chance that the needle placed in the vein may infiltrate (become blocked or make a hole in the wall of the vein) causing temporary swelling, bruising, bleeding and/or discomfort.

You also will receive an arterial line placed in your wrist prior to the scan. Risks include pain, bleeding, temporary blockage of the artery, and skin infection. Rare complications associated with arterial catheters include abscess, paralysis of the median nerve, suppurative thromboarteritis, air embolism, compartment syndrome and carpal tunnel syndrome. However, these risks are quite small and these problems can be treated. Even though your skin will be anesthetized, you may still feel pain or discomfort at the site of the arterial catheter. The line will be placed by a medical staff member who has considerable experience in the placement of arterial lines. Following removal of the line, a pressure bandage will be placed on your wrist for one hour. You will remain under observation for one hour in the PET Center.

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection. A maximum of about 300 mL (or about 1 ¼ cups) of blood will be taken during the entire study. This is less than the amount taken for routine blood donation.

Radiation Exposure
This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays from natural sources (like the sun, outer space, air, food and soil) or medical sources can damage the genetic material (DNA) in your cells. At low doses, the body is usually able to repair the damage.

The radiation exposure that you will get in this research study from the PET imaging procedures will be about 0.95 rem (a rem is a unit of absorbed radiation). This is less than the 5 rems of radiation that is allowed each year for people who are exposed to radiation in their jobs.

If you also require skull x-rays to determine if you have metal in your head or eye prior to the MRI scan, you will have an additional 0.01 rem of radiation exposure. The total amount of radiation exposure you will receive is about 0.96 rem to your whole body. If you are found to have metal in your head or eye, then you will not be allowed to continue in the study.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

Lidocaine:
Lidocaine is used to numb your arm prior to placement of the arterial catheter. There is a chance you could have an allergic reaction to lidocaine. You must tell the study doctor if you have ever had an allergic reaction to lidocaine. The highest dose of lidocaine you will receive in this study is 10% of the

largest recommended dose. This dose is also only 5% of the dose at which any side effects would be expected. These side effects include drowsiness or tremors (shakiness). Since the dose is so small, side effects are unlikely.

Thermoplastic Facemask:
Your facemask may cause you some discomfort. If the mask is too tight, please tell us and we will remold it, or we will reposition you in the scanner. You may experience some irritation of the skin when the facemask is made.

PET Table:
During the PET scan that you may find lying on the scanner tables to be uncomfortable. If you have back problems, please tell us so we can determine if you will be able to complete the study. If you feel discomfort, we will attempt to reposition you and cushion you with padding to make you more comfortable.

^{18}F-ASEM
The dose of ^{18}F-ASEM is not expected to have any effect on body function.

Occasionally, people have allergic reactions to medications. A severe allergic reaction could be life threatening.

- Examples of an allergic reaction include:
- a rash
- shortness of breath
- wheezing
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You must let your study doctor or study team member know immediately if you have any of these symptoms.

Interviews or questionnaires
Many of the evaluations and questionnaires used in this study include questions that are personal. You will be asked specifically about your psychiatric history, medical history and drug use history. This may make you feel uncomfortable or upset. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

6. Are there risks related to pregnancy?

Pregnant women cannot be in this study. If you can still get pregnant, you must use a method of birth control or not be currently sexually active during the study.

You must be willing to take pregnancy tests during the screening visit and at study visits. A urine pregnancy test will be performed at the time of the screening, and before the MRI and PET procedures; a blood pregnancy test will also be performed before the MRI.

If you become pregnant (or suspect pregnancy), inform the study doctor immediately. If you become pregnant, the study procedures will be stopped, and we will encourage you to contact your doctor.

There are no known risks associated with having MRI imaging without contrast during pregnancy. There may be risks that are unknown.

Radiation exposure associated with the scans may be harmful to a fetus and this research may hurt an embryo or fetus in ways we do not currently know.

7. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. By taking part in this study, you will help us better understand the brain chemistry of cigarette smokers. If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

On the day of your screening visit, you will be paid $40 for completing the assessment procedures. It is possible that we may not be able to complete all eligibility procedures at your first visit. If we need you to come in a second time to complete additional procedures, you will be paid an additional $25. You will be paid in cash for the initial screening procedures.

Following this initial screening, we will determine your eligibility to continue in the study. If you join the study, you will receive $125 for completion of the MRI and baseline assessment procedures when smoking as usual (study visit 1), and your payments for study visits 2 and 3 will be different depending on whether you have maintained not smoking cigarettes. You will receive $40 for visit 2 during the 8-day quit attempt and will receive a bonus payment ($75) if our measures tell us you have been able to maintain not smoking. If our tests tell us you have not successfully quit smoking, we may decide to remove you from the study. You must be able to not smoke for at least 1 day in order to complete the PET scan which will take place on day 1 of the 8-day quit attempt. If you complete the PET scan, you will receive $40 to attend Visit 3, and will receive a bonus payment ($75) if our measures tell us you have been able to maintain not smoking. You will also receive a $50 study completion bonus, and are eligible for this bonus even if you are unable to quit smoking after completion of the PET scan. The balance of the payments for study procedures will be made to you after each study visit. Payments greater than $50 will be made by check.

STUDY VISITS	Procedure	Payment	Incentive bonus (not smoking)	Maximum visit payment
Visit 1 Smoking as Usual	Assessments	$40	not applicable	$125
	MRI	$85		
Visit 2 - Practice Quit Day 1	Assessments	$40	$75	$315
	PET scan	$200		
Visit 3- Practice Quit Day 8	Assessments	$40	$75	$115
Completion Bonus				$50
Subtotal				$605
Typical Total compensation with Screening visit				**$645**
Max Compensation with extra visit		$25		$670

If you drop out of the study, you will be paid for completed procedures but will forfeit future possible earnings. If the investigator decides that it is no longer safe for you to be in the study, you will be paid the money you have earned for completed procedures, and you may still get a bonus payment based on the amount of time you have been in the study.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information they have already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.

- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that they have already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Your name will be recorded only on the screening, informed consent, and necessary medical and payment forms. Anonymous participant identification numbers will be used on all other forms and labeling of biological fluids and test results. All information gathered will be kept in locked research staff offices or file cabinets. Only research staff will have access to participant research records. Study findings are reported using group data only.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

16. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

17. What other things should you know about this research study?

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you.

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Weerts at 410-550-2781. If you wish, you may also contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Denis Antoine, M.D. M.D. at at 667-208-8069 during regular office hours or at 202-494-0289 after hours and on weekends.

If neither Dr. Antoine nor Dr. Weerts is available at the time of your call, please leave a message for them and then call your primary care physician and be sure to let him/her know that you are participating in a research study. If it is an emergency, call 911 and seek immediate medical attention.

18. Optional Study Components:

Future Contact

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please check box and sign to indicate your choice below:

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

19. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).