**Consent to be a Research Subject**

**You Are Being Asked to Be in a Research Study**

**Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of INSERT NUMBER people who are being studied at the Atlanta VA Health Care System.

**Why is this study being done?**

This study is being done to answer the question: INSERT QUESTION HERE. You are being asked to be in this research study because INSERT REASON HERE.

**Do you have to be in the study?**

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

**What do I have to do if I choose to participate in this study?**

If you are eligible and want to be part of the study, you will participate for XXX (XXX study visits). The researchers will ask you to do the following: INSERT.

**How is this study going to help you?**

If you are in the study, you will be helping the researchers answer the study question. INSERT OTHER BENEFITS IF APPLICABLE.

**What are the risks or discomforts I should know about before making a decision?**

The study will take time. The drug/device/procedure that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include [risks of the DRUG/DEVICE/PROCEDURE, SOME OF WHICH INCLUDE], loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the RISKS section of this document.

**Alternatives to Joining This Study**

[Describe alternative treatments here, specific to the enrolling institution, or say “Since this is not a treatment study, the alternative is not to participate”).

**What Should I Do Next?**

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

**TITLE:**

**PRINCIPAL INVESTIGATOR:**

**SPONSOR'S NAME:**

**PURPOSE:**

You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

• Please carefully read this form or have it read to you

• Please listen to the study doctor or study staff explain the study to you

• Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

The purpose of this study is to:

**CLINICALTRIALS.GOV:**.

**WHAT WILL I BE ASKED TO DO?:**

**RISKS:**

**There may be side effects from the study drug or procedures that are not known at this time.**

**The most common risks and discomforts expected in this study are:**

**The less common risks and discomforts expected in this study are:**

**Rare but possible risks include:**

**REPRODUCTIVE RISKS:**

**It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.**

**BENEFITS:**

**COMPENSATION:**

**COSTS:**

**You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.**

**The VA will provide the necessary medical treatment if you get injured from being in this study. This requirement does not apply to:**

1. **Treatment for injuries due to non-compliance by a subject with study procedures;**

**Or**

**(2) Research conducted for VA under a contract with an individual or a non-VA institution.**

**If you believe you have been injured by this research, you should contact** [name of VA PI] **at ###-###-####**.

**ALTERNATIVES:**

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED:**

**We will keep information about you, including any research records we create, strictly confidential to the extent required by law.**

**We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use [a study number\*] rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results.” People other than those doing this research study may have access to your medical and study records including:**

* **Sponsors, companies or agencies paying for the study**
* **The Office for Human Research Protections**
* **The Government Accountability Office (GAO)**
* **The Inspector General**
* **Emory University**
* **Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above**

**All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.**

**If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s)**. **If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.**

**If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.**

**HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):**

**There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your ‘authorization,’ for the use and disclosure of information protected by the HIPAA Privacy Rule.**

**The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as** medical history, allergies, lab results, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

**The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include** the Office of Human Research Protections (OHRP), the Inspector General, and the Government Accountability Office (GAO).

**Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.**

**You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.**

**If you revoke this authorization,** [name and address of VA PI] **and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.**

**Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.**

**RESULTS:**

**CERTIFICATE OF CONFIDENTIALITY:**

**BIOSPECIMENS:**

**IDENTIFIABLE PRIVATE INFORMATION OR IDENTFIABLE SPECIMENS:**

**CONFLICT OF INTEREST:**

**CONTACT PERSONS:**

**If you have any questions, concerns, or complaints about this study you can call a member of the study staff**: [Contact can be the VA PI and/or VA study coordinator] at ###-###-####

**If you have been harmed from being in this study call:** [name of VA PI] at ###-###-####

**If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:**

**The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Manager at (404) 321-6111 ext. 206933.**

**If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.**

**VOLUNTARY PARTICIPATION AND WITHDRAWAL:**

**The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.**

**Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.** **For your safety, however, you should consider the study doctor’s advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:**

* **EXAMPLE-Imaging, lab work, etc.**

**The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.**

**We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.**

**RESEARCH PARTICIPANT’S SIGNATURE AND DATE:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Research Participant’s name

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

Research Participant’s Signature Date