Name of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Age: \_\_\_\_\_\_\_\_\_\_\_

Greetings, thank you for your interest. This form tells you about our research study. Please read carefully. We are happy to answer any questions. You will be given a copy of this consent form.

**Key Information:**

*Instructions: This section should provide a brief overview of the study and should highlight the reasons that a person may or may not want to participate in the study. Generally, this section should describe what participants are going to do and what the potential benefits and risks are. All of the information provided in this section should still be described in further detail in the body of the consent document (think of it like an abstract for your informed consent document). Depending on the complexity of the research study and procedures involved, this section may be brief (a few sentences) or lengthier (more than one paragraph). For additional guidance and examples, please refer to the “Tip Sheet for Key Information” document located on the HRPP website under Consent Document Resources.*

**Detailed Information:**

**Why are we doing this research and why are you asked to participate?**

You are being asked to take part in this research study because…

Do you have to be in this research and can you stop if you want to?

You do not have to be in this research study, and you can stop being in this study at any time. *[For research that involves medical, therapeutic, or interventional treatment, include the following*]: You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. [*For research that does not involve medical, therapeutic, or interventional treatment, include the following*]: You may choose not to be in this study. This is not a treatment study, so there are no alternative treatments.

[*Insert if applicable*]: If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

[*Insert if medical records will be accessed*]: Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

**What will you do and how long will it take?**

*[Insert a detailed description of all study procedures and total time commitment, including passive involvement by the participant such as collecting data from a record]*

**What are the costs?**

*[If there are no costs to the participant or a third party, this section can be removed]*

**What good things might come from this study?**

a) The benefits to science and humankind that might result from this study:

b) The benefits you might get from being in this study:

**Are there any risks or discomforts for this study? Can anything bad happen to you?**

*[Insert a description of all potential risks/discomforts. Even minimal risk research has potential risks. For example, feelings of sadness or discomfort when completing a survey, the risk of a breach of confidentiality, etc.]*

**What are the unforeseeable risks?**

*[Insert the following language only if applicable (e.g. clinical trials).]:* Because this treatment is investigational, meaning non-FDA approved, there may be unknown or unforeseeable risks associated with participation.

*[If the above statement does not apply, include the following*]: There may be risks that we do not know about.

**Is there compensation in case of study-related injury?**

*[Insert only if applicable, (e.g., if conducting clinical interventions**). This section can be removed if it is not applicable]*

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

**How can you find out the results of the study?**

*[Insert a statement of how results will be shared or not shared with participants and under what conditions, if applicable.*]

**What are the alternatives to participating?**

*[If other treatment(s) exist, explain what these are. If this study does not involve treatment, include a description of the alternative activities participants may undergo if they choose not to participate in the research. For example, if research is being done in a classroom, describe the alternate activities the student will do if they don’t participate in the research.]*

**What compensation will you receive for participating in the study?**

*[Describe the compensation, if any, that participants will receive. This includes forms of payment such as gift cards, course credits, etc. If there is no compensation, you can delete this section.]*

*[Insert the following language if you are a VUMC researcher and are providing any compensation, VU researchers do not need to include this paragraph]*

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws.  You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government‘s comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department’s Office of Foreign Assets Control’s Specially Designated Nationals (SDN) list of prohibited individuals.  You do not have to say why you choose not to be paid.

**Are there any reasons the researchers may remove you from the study?**

**What happens if you choose to stop being in the study?**

**Who can you talk to about this study?**

If you should have any questions about this research study or possibly injury, please feel free to contact **(INSERT NAME OF RESEARCHER)** at **(INSERT RESEARCHER’S PHONE NUMBER)** or my Faculty Advisor**, (INSERT NAME OF FACULTY ADVISOR)** at **(INSERT FACULTY ADVISOR’S NUMBER)**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**How will your confidentiality and privacy be maintained?**

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

*[Insert a description of how records and data/specimens will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality. See the description and examples in the IRB application for guidance.]*

*[If any data will go into or come from VUMC’s medical record, please insert the following standard HIPAA Authorization language. This language be included in its entirety with no revisions. This language should not be included if medical records will not be accessed, and you should skip to “STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY”]:*

**Authorization to Use/Disclose 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 Vanderbilt University Medical Center 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.  Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight.  By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center.  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, insurance providers 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.

*[OPTIONAL: You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.]*

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

**STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY**

**[ ]  I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.**

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

 Printed Name and Title