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

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

**Key Information:**

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

**Key information about this study:**

*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. Examples of this information are: The participant may/may not benefit from the study and some of the potential benefits; What are some potential risks?; Time Commitment (number of visits, amount of time visits may take); Limitations on daily activities (not driving on the day of a visit); Restrictions (not taking medications, fasting before a visit, avoiding certain foods); Performing a certain activity for an extended period of time (eating an M&M every day); Potential costs; Drug is/is not FDA approved; Exposure to radiation; the participant will also be asked to participate in sub-studies.*

**Detailed Information:**

The rest of this document includes detailed information about this study (in addition to the information listed above).

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

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. 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. 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.

**Side effects and risks that you can expect if you take part in this study:**

*[This is a more detailed list of effects than what is provided above. It is helpful if side effects are categorized as common (>10%), uncommon (<10%) or rare (<1%); however, identifying each of those that may be severe and/or life threatening is required.]*

**Risks that are not known:**

*[Insert if applicable]:* Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

**Other Risks:**

*[Insert any of the below if genetic information is produced, this may not be applicable for personalized medicine testing:]* One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only (investigator’s name and/or other’s names) will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

**Good effects that might result from this study:**

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

**Procedures to be followed:**

*[Insert genetic information, if applicable.]*

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person’s risk for certain diseases and how they will respond to treatment.

You are being asked to give a *[Insert type of sample, e.g. blood, urine, etc.]* for genetic research. What we learn about you from this sample (will not be) or (may be) put in your health record. [*If applicable insert:* Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.]

**Payments for your time spent taking part in this study or expenses:**

*[Insert if you are a VUMC researcher and are providing any compensation*; *Insert a brief description of payments to participants and add the paragraph below, indicate no payments or delete if not applicable.]*

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.

**Costs to you if you take part in this study:**

*If there is no billing to the participant or insurance, the following template should be used:*

There is no cost to you for taking part in this study.

***OR***

*If there is billing to the participant or insurance, the following template should be used:*

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

**Payment in case you are injured because of this research study:**

**This language is applicable to most studies:**

*If there may be billing to the participant or insurance, the following template should be used. This option should be used unless the Sponsor will provide full coverage for subject injury and this is outlined in the contract:*

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.

***OR***

**This language may be applicable in certain instances:**

*If there is no potential billing to the participant or insurance (i.e. the Sponsor will provide full coverage for subject injury and this is outlined in the contract), the following template should be used:*

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

**Who to call for any questions or in case you are injured:**

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, 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)**. **(INSERT IF EMERGENCY CONTACT IS DIFFERENT FROM THE INVESTIGATOR).** If you cannot reach the research staff, please page the study doctor at **(INSERT INVESTIGATOR’S PAGER NUMBER)**.

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

**Reasons why the study doctor may take you out of this study:**

*[Insert if applicable]*

**What will happen if you decide to stop being in this study?**

***This language is OPTIONAL for therapeutic trials:***

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

***This language is OPTIONAL for non-therapeutic trials:***

If you decide to stop being part of the study, you should tell your study doctor.

**Clinical Trials Registry:**

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

**Confidentiality:**

*[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.]*

*[Insert this language if the study receives any funding from the NIH including]*

This study may have some support from the National Institutes of Health (NIH). If so, 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, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

**Privacy:**

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

***Insert if collecting and storing specimens for future research:***

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you. *Indicate if the research will include whole genome sequencing (human germline or somatic specimen with the intent to generate genome or exome sequencing).*

At any time, you may ask to have your sample destroyed. You should contact [PI name or study staff] at [insert address/phone number] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. [Insert if applicable: You will not be paid for the use of your samples.]

**Study Results:**

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

**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 BE IN THIS STUDY

**I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.**

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title

Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Time is an optional field. When used, this field should be completed by the person obtaining consent.]