Part 1 of 2: MASTER CONSENT

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

***You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.***

**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.

**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.

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

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

**Procedures to be followed:**

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

*[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.

**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, or use the bio/data repository rider:**

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, 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).*

**Study Results:**

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