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

*Guidance for investigator (delete this section prior to use):*

* *This simplified assent form is recommended for children ages 13-17 who will not turn 18 while on the study; however, it is the responsibility of the investigator to utilize the assent form that best facilitates understanding of the research for an individual participant.*
* *For 13-17 year olds who will turn 18 while on study, it is recommended that the other assent form template on the HRPP website be utilized instead of this simplified form, as adult concepts such as Cost and Payment in Case of Injury may be applicable to the child when they turn 18.*
* *Assent of older children (e.g. ages 13-17) whose capacity to understand resembles that of adults should closely mimic the content and language of the adult consent, as the adult consent form should already be written at approximately a sixth to eighth grade reading level (HRPP Procedure IV.A.2).*
* *The below template closely mimics the adult consent form, with the exception of a few topics that the VUMC IRB acknowledges may not be applicable to children. For example, the cost language section is not included in this Assent Form, as children should not have to deal with the financial aspects of a study.*
* *Please refer to the Children in Research FAQ page on the HRPP website for additional information and guidance.*

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 assent 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); Exposure to radiation; the participant will also be asked to participate in sub-studies. For additional guidance and examples, please refer to the “Tip Sheet for Key Information” document located on the HRPP website under “Template Documents” then “Additional Consent Document Resources*.

**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 or your parent 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 in the Key Information section. All risks must be stated; however, it is helpful if side effects are categorized as common (>10%), uncommon (<10%) or rare (<1%). Identifying each of those that may be severe and/or life threatening is required.]*

**Risks that are not known:**

*[Insert if investigational procedures are part of the research]:* Because this is a research study, 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.

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 a description of all study procedures]*

*[Insert below 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 a brief description of payments to participants, indicate no payments or delete if not applicable.]*

**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:

* **(PI Name)** at **(PI Phone Number)** or **(Faculty Advisor Name)** at **(Faculty Advisor Phone Number)**.

[*Insert if applicable:*] If you cannot reach the research staff, please page the study doctor at **(Study Doctor Pager Number)**.

For additional information about giving assent 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 team. 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 team.

**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]*

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 assent 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.

At any time, you or your parent may ask to have your sample destroyed. You or your parent 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.

**Study Results:**

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

# STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

**I have read this assent 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 or printed name of patient/volunteer

Assent 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 assent.]