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.*

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 assent 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 assent document (think of it like an abstract for your assent 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 “Template Documents” then “Additional 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 or your parent 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 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 if applicable]:* Because this is a research study, there may be risks that we do not know about at this time.

**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.]*

**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 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 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.]*

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

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

Assent obtained by:

Date Signature

Printed Name and Title