YOUTH ASSENT FORM

**STUDY TITLE:** [Insert the official title of the study, as it is given in the IRB application]

**RESEARCHER’S NAME:** [Insert the full name and title of the VCU Principal Investigator]

*TEMPLATE INSTRUCTIONS:*

* Instructions and comments are indicated in blue boxes and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Example text should be edited to be appropriate for your study.
* **Use simple language at the reading level of the youngest child who will use this assent form.** For example, if the youngest participant will be 7 years old, then it should have a 2nd grade reading level.
* **The language used in this template is written at approximately the 6th grade level.**
* The internet offers many free readability tools (Google “readability checker”)
* Or turn on the readability statistics option in Word to show readability scores after spelling/grammar check is finished (See [Microsoft Office Support](https://support.office.com/en-us/article/Test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2) for instructions)
* If it is necessary to use technical terms, a lay definition of the term must be provided.
* Define all acronyms at first use.
* Page numbers must be included in the format “Page \_\_ out of \_\_\_\_”.

**Why are we meeting with you?**

I am asking you and other children/teenagers to take part in a research study. A research study is a way to learn more about something. You are being asked to join this research study because [insert name of condition/reason for inclusion]. After we tell you about it, we will ask if you’d like to be in this study or not.

This form may have some words that you do not know. Please ask me to explain any words that you do not know. You may take this form home to think about and talk to your parents about before you decide if you want to be in this study.

**What is this study about?**

INSTRUCTIONS: Briefly fill in purpose of the study in language that a young person could understand.

[Example:] We are doing this study to find out what problems teenagers have. The study will also try to find out how teens work out their problems.

[Example:] We want to find out how well your kind of cancer treatment is working.

**What will happen to me if I choose to be in this study?**

INSTRUCTIONS: List all the types of activities that participants will be asked to do. Include the number of visits and time frame in words easily understood by a child.

[Example:] In this study, you will be asked to:

1. Work with a teacher either in a group with other kids or just you and the teacher
2. Answer questions about [describe general topics]
3. Take math and reading tests \_\_ times at school

[Example:] Before the study begins:

1. The study doctor will ask your parents some questions about you.
2. The study doctor will ask you questions about your health.
3. You will have a physical exam, and you will give some urine and some blood for the doctors to test.
4. A small amount of your blood will be drawn. That means it will be taken by a needle in your arm. This will happen every 3 months for one year.
5. Some of the urine collected from you will be tested for illegal drugs, in order to see if you can be included in the study. If any illegal drugs are found in your urine, you and your parents will be told, and you won’t be able to be in the study.

During the study:

1. Then you will start taking one study pill every morning. You will get either [study drug] pills or placebo pills (pills that have no effect). You will not know which kind of pills you are taking, and neither will your doctors or your parents, until the end of the study.
2. During the 16 weeks of the study, you will need to visit the clinic at least 11 more times for physical exams and blood tests. Each visit will last 1 to 3 hours.

[Example:] In this study, you will go to two group meetings. Each meeting will be about one hour. In each meeting, you will be in a group with 8 or 9 other teenagers. In the first meeting you will be asked to talk about things like sex, drugs and school. [Provide examples of the types of questions you will be asking/content that will be discussed.] In the second meeting you will be asked to talk about your friends and family. We will record your voice during the meetings so we are sure to get everyone’s ideas. We will not record your name.

**Will any parts of this study make me feel bad?**

INSTRUCTIONS: Explain the possible risks or discomforts (physical and psychological) and how they will be handled:

[Example:] Sometimes talking about these things makes people upset. You do not have to talk about anything you do not want to talk about. You can leave the group at any time. If you do become upset, the people running the group will help you.

[Example:] It will hurt a little when we take blood from your arm, but we will help you to feel better.

[Example:] Sometimes when the sticky patches for the ECG are taken off they can hurt a little bit. It is like when a bandage is pulled off your skin.

[Example:] You may have side effects from the study medicine. If you feel any side effects, you should tell your parents or the study doctor about this right away.

[Example:] If you were taking medicine for your ADHD before, and you get the placebo pills in the study, it might turn out the placebo pills don’t help you as much as your old medicine did.

**Will I get better if I am in this study? OR How will this study help me?**

INSTRUCTIONS: Describe any benefits to the child. Use any of the following statements that are appropriate.

[Example:] We do not know if being in this study will help you.

[Example:] We expect that the study will help you by [describe how].

[Example:] No, this study won’t make you feel better or get well. But the doctors might find out something that will help other children like you later.

[Example:] We may learn something that will help other children with [insert name of condition or topic under investigation] in the future.

[Example:] This study will help us learn more about [condition/disease under study].

**What do I get if I am in this study?**

INSTRUCTIONS: This section is optional. You only need to have this section if you are providing compensation to the participants. If you are paying for participation or giving small gifts, you must be very specific as to the amount, how it will be paid, and whether the payment will be given to the parent or to the child.

[Example:] You get a $5.00 gift certificate to the mall for each time you come to the group.

**Will you tell anyone what I say?**

We will not tell anyone the answers you give us. However, other members of your group will know what you say. We will not share your answers with your teachers, parents, or friends. [If information will be shared with parents (e.g. pregnancy test results, grades, etc.) then that should be described.]

If you tell us that someone is hurting you, the law says that we have to let other people know so they can help you. If you tell us that you might hurt yourself or someone else, then we have to let people know.

**Do I have to be in this study?**

You do not have to be in this study. It is up to you. You can say okay now and change your mind later. No one will blame you or get mad at you if you don’t want to do this.All you have to do is tell us you want to stop.

**Do you have any questions?**

You can ask questions at any time. You can ask now or later. Just tell the researcher when you see them, or ask your parent or another adult call [Give the name of the contact person and his/her contact information here].

Before you say **yes or no** to being in this study, we will answer any questions you have now.

**If you don’t want to be in this study, just say so, and don’t sign this form.**

**YOUTH ASSENT**

**Try to format the signature lines so that all signatures fit on a single page.**

\*\*If you sign here, it means you agree to participate in this study.

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Youth Participant’s Name (Printed) Date

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Youth Participant’s Signature Date

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Name of Person Conducting Assent Discussion (Printed)

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Signature of Person Conducting Assent Discussion Date

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Principal Investigator Signature (if different from above) Date