



ASSENT FORM (ages 13-17)

Title: [Insert Name]

Study Investigator: [Insert Name]

Why am I here?

This is a research study. Only people who choose to take part are included in research studies. You are being asked to take part in this study because [insert reason for selection]. Please take time to make your decision. Talk to your family about it and be sure to ask questions about anything you don't understand.

Why are they doing this study?

This study is being done to find out [insert purpose of study]

What will happen to me?

[Describe what will take place from the child's point of view in language that is both appropriate to the child's maturity and age]

How long will I be in the study?

You will be in the study for [describe how long and how often visits will occur].

Will the study help me?

Select appropriate selection

- "You [choose correct verbiage may/will] not benefit from being in this study; however information from this study may help other people in the future [explain aim(s)]."
- "You may benefit from being in this study [describe any direct benefit to the participant].
If there is also an indirect benefit please add: "Information gained from this study may help other people in the future [explain aim(s)]."

Will anything bad happen to me?

Describe any risks appropriate for the child's age and maturity

What other options are there? [Delete if not an intervention/treatment study]

{List Options in Bullet Points}

Will I get paid to be in the study?

If there is no compensation please remove header. Note that participants are not paid for participation, but are compensated for their time and inconvenience.

For taking part in this research study, you will receive [enter form, amount if applicable and schedule] All payments to participants should be prorated for partial participation. Payment schedule should be listed.]

Do my parents or guardians know about this? (If applicable)

This study information has been given to your parents/guardian. You can talk this over with them before you decide.

What about confidentiality?

Every reasonable effort will be made to keep your records (medical or other) and/or your information confidential, however we do have to let some people look at your study records.

We will keep your records private unless we are required by law to share any information. The law says we have to tell someone if you might hurt yourself or someone else. The study doctor can use the study results as long as you cannot be identified.

What if I have any questions?

For questions about the study please call [Insert PI's name] at [insert PI's phone number].

Do I have to be in the study?

You don't have to be in this study if you don't want to or you can stop being in the study at any time. Please discuss your decision with your parents and researcher. No one will be angry if you decide to stop being in the study.

ASSENT FOR PARTICIPATION IN THE STUDY

I / my parent or legal guardian has read the previous page(s) of the consent form and the investigator has explained the details of the study. I/my parent or legal guardian understands that I am free to ask additional questions.

I/my parent or guardian understands that participation in this study entitled [insert name of study] is voluntary and I/my parent or legal guardian may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I/my parent or legal guardian, acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I agree to participate in the study and have been given a copy of this form.

Signature of Participant

Date

Printed name of Participant

Signature of Person who explained this form

Date

Printed Name of Person who explained form