**CHILD ASSENT FORM**

**Title:**

**Protocol No.:**

**Investigator:** Name

**study-related**

**phone number(s):** Name

Phone number (24-hour number required)

What is a research study?

A research study is something like a science project at school, but harder to do. When doctors and scientists want to learn more about a medicine, they have to test it on people to see if the medicine helps people and to make sure that it does not hurt them.

Why do you want me to be in this study?

What do I have to do?

If you choose to be in this study, Dr. [study doctor name] or the study staff will:

* Ask you questions about how you are feeling
* Ask you questions about what other medicines you are taking

You can ask any questions you want before you decide if you want to be in this study. The study doctor or staff will answer your questions.

What if I do not want to be in this study?

* You get to decide if you want to take part.
* You can say ‘No’ or you can say ‘Yes’.
* No one will be upset if you say ‘No’.
* If you say ‘Yes’, you can always say ‘No’ later.
* You can say ‘No’ at any time.
* We would still take good care of you no matter what you decide.

Will I get anything for being in this study?

If you decide to be in this study, you will get study medicine for free. You will also get care from the study doctor and staff.

Will the study help me?

We do not know if this study will help you. We may learn something that will help other children and teenagers like you.

Could I be hurt if I am in this study

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

If you feel sick or are afraid that something is wrong with you, tell a grown-up as soon as you can.

You and your parent(s)/guardian(s) will be given any new information that may come up during the study that might change your mind about staying in the study.

**Information about birth control and pregnancy (females who already had their periods):**

You cannot be in this study if you are pregnant or breastfeeding. The study drug might hurt you or the baby if you get pregnant. There may be unwanted things that happen to you or your baby which are not known at this time. It is very important that you do not become pregnant while you are in this study. If you have gotten your period, pregnancy tests will be done using your urine or your blood.

If you are having vaginal sex with a male, you will have to use birth control to keep from getting pregnant to be in this study. The study doctor and your parents or guardians will explain what you need to do.

If you think you might be pregnant, you must tell the study doctor or study team right away. If you are pregnant, the study drug will be stopped.

Will your information be kept secret?

What else should I know if I am in this study?

You can ask questions any time. You can talk to Dr. [study doctor name] or the study staff.

Ask us any questions you have. Take the time you need to make your choice.

**ASSENT TO BE IN THE STUDY**

If you want to be in the research after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.:

**Subject**

Your Name (Printing is OK) Date

**Person Obtaining Assent**

Printed Name & Title Signature Date