

Insert the upper age in the title and adjust language to correspond with the specific protocol requirements.

**CHILDREN'S ASSENT FORM
(For Subjects 10 to [] Years of Age)**

STUDY TITLE:

STUDY #:

SPONSOR:

STUDY DOCTOR:

RESEARCH SITE ADDRESS(ES):

DAYTIME TELEPHONE NUMBER(S):

24-HOUR CONTACT NUMBER(S):

You are being asked to take part in a research study of a study medicine. This is because you have []. Before you decide if you want to be in this study, we want to tell you about the medicine. This is so you can ask questions.

If you want to read more about the study, ask for a copy of the form that your parent will read and sign.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to see how safe the study medicine is and how well it works for people who have [].

The study medicine is taken []. You may be given a placebo. A placebo is like the study medicine but does not have the study medicine in it. You and your doctor will not be able to tell which of these you receive. Your doctor can find out if he or she needs to know.

Girls in this study should not get pregnant. If you are a girl and you have ever had your period, the doctor will discuss this with you.

You will be tested to see if you are pregnant during this study. If you are pregnant, the doctor may tell your parents.

You should not take part in this study if you don't want a pregnancy test.

Boys in this study should not get girls pregnant. The doctor will discuss this with you.

WHAT WILL I BE ASKED TO DO?

The study lasts [] weeks. You will need to come to the clinic about [] times.

List study specifics here

CAN BAD THINGS HAPPEN TO ME DURING THE STUDY?

List risks here

Example: After using _____, some people have had _____.

You may have some of these problems, too. You may have other feelings or problems that have not happened before. Tell your parents and tell your doctor or nurse if you feel sick during the study. Tell them if you want to stop being in this study.

When you have your blood taken from your arm:

- it may hurt
- you may get a bruise at the place where the blood is taken
- you might feel dizzy
- you might get an infection where the blood is taken

If you get pregnant, the medicine could hurt the baby.

WILL BEING IN THE STUDY HELP ME?

Use the most appropriate statement depending on the phase of the study and what is known about the study medicine:

We do not know if being in this study will help you.

We have used this study medicine in other people **your age**. Being in this study may not make you feel better.

This study may help you by _____.

DO I HAVE TO BE IN THE STUDY?

You do not have to be in the study. You can stop at any time. No one will be upset with you or your parents.

If you stop being in the study, this will not change the way your doctor treats you.

Your doctor will help decide which medicine is best to use after you finish the study.

Tell your parents, doctor or nurse about any parts of the study that make you feel bad. The doctor or nurse will answer any questions you have.

SUBJECT'S ASSENT (10 – XX years)

Insert Study Title here in italics

- I have read this form or had it read to me.
- I don't have to be in this study if I don't want to.
- I can stop at any time and no one will be upset with me.
- My doctor will still take care of me.
- My parent(s) may be told if I am pregnant.
- I have asked any questions I have so far about the study.
- My questions have been answered.

I agree to take part in this study.

Child's Name (*please print*)

Signature of Child, as able

Date

I explained the study in language understood by the child.

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date