TEMPLATE ASSENT – This document is the framework for a complete assent form. Site-specific information and study-specific information (from sponsor template) should be inserted as appropriate.

* Assent should be ~2 pages with font size 12-14 point.
* Assent can also be written in 2nd person (You can say No. What will happen to you?)
* Please see the embedded comments and notes for additional guidance.
* Be sure to keep the “Tracked Changes” feature ON.
* Delete any notes and comments in this form.

## **INSTITUTION**

## **ASSENT FORM - Children Ages 7 - 12 Years**

## Protocol Title:

## Protocol #:

## Sponsor:

## Study Doctor:

## Institution:

## Address:

## Telephone:

* I was told I can be in a research study because I have XXXXX (e.g. HIV; kidney disease).
* I can say "Yes" or "No" to being in this study.
* I can ask as many questions as I like before I decide.

**Why is the study being done?**

The study may help scientists learn more about XXXXXX. The scientists are testing a drug and want to find out if it is safe to give to children.

[Use simple descriptions, e.g. in a study of immune function: Scientists want to find out how the body fights disease.]

About ### other children and adults will be in this study around the world.

**What will happen if I am in this study?**

Not all procedures from the consent should be in the assent - include only basic/important procedures. Use pregnancy bullets only as needed.

EXAMPLES below (delete/edit as applicable):

* I will be in the study for about ### (e.g. 2 months; 1 year).
* I will come to the clinic about ## times.
* The doctor or nurse will ask me how I am feeling and what medicines I am taking.
* I will have a physical exam (check-up).
* My heart, breathing, temperature and weight will be checked.
* About ## teaspoon of blood will be taken from my arm using a needle.
* I will be asked to pee in a cup for tests on my urine.
* I will be given the study drug as a shot into my thigh. I will get one shot at every visit which will be 4 shots altogether.
* The study drug is a pill. I will swallow one pill every morning every day for 3 weeks.
* I will be given the study drug through a thin tube put under my skin. It will take about 20 minutes.
* (For randomized trial) I will be given one of two drugs. One drug is a new drug. The other is the regular medicine for people with my type of disease.

**Can I get hurt in the study?**

Not all risks from the consent should be in the assent - include only basic/important risks and simplify.

Examples - edit as applicable:

* The study drug might make me feel sick. I might get\_\_\_\_\_\_\_ (e.g., a headache, throw up, get confused, or feel very tired).
* The needle will hurt like a pinch and I might get a bruise or feel dizzy. The hurt will go away after a little while.

I should tell the doctor, nurse or my parent or guardian anytime I feel sick or if any of the tests hurt me.

**Will this study help me?**

Being in this study might not help me. But my doctor hopes to learn more about my disease so that it might help other children in the future.

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

* I do not have to be in this study, even if my parent or guardian wants me to be.
* I can say "No." No one will be mad at me. The doctors will still take care of me.
* If I say “Yes” now, I can change my mind at any time. I just have to tell the doctor, nurse or my parent or guardian that I want to stop. I don’t have to say why.

I can talk to my parents and the doctor about the study at any time and ask them questions at any time.

**YES**, I want to be in the study. (Then fill in your name below.)

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Child: Print your name Sign your name (if able) Date

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Witness: Print Name Signature Date

Witness must be a third party unrelated to the subject

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Person Obtaining Assent: Print Name Signature Date