Instructions for Creating a Child Assent Form:

- This form provides suggestions for preparing assent forms. Studies vary significantly; deviations may be necessary.
- Instructions to investigators are in italicized type and should be deleted.
- Final text should be 14pt or larger. Each sentence or closely-related group of sentences should be a paragraph visibly separated from other paragraphs.
- For Central IRB approved studies, the local IRB defers to the Central IRB on their approved age of assent.

[Insert Name of Institution]

TITLE OF STUDY

Assent Form for Minors Age 12 and Above

I was told I can be in a research study. I can say yes or I can say no. I can ask as many questions as I like before I decide.

The study may help scientists learn more about _______.

Describe the study topic in the simplest terms possible, e.g.

- for a study of immune function, add “how the body fights disease.”
- for a study of cancer, add “cancer.”

If I am in the study, the scientist will___________.

Describe briefly the basic elements of the study from the perspective of the participant using short, subject-verb sentences. For many studies there will be only one sentence. For complicated clinical trials there should be at most 5-10 sentences. e.g.

- for a study involving only an additional blood draw, add “use a needle to take some blood from my arm.”
- for a randomized trial of two chemotherapeutic agents, add “give me one of two medicines. One medicine is a new medicine. The other is the regular medicine for people with my type of cancer. The medicine will be given for one hour through a needle in my arm. This will happen 2 times a week for 2 months.”

Describe the principal study related risk(s), e.g.

- for a study involving only an additional blood draw, “Drawing blood may hurt me where the needle goes in. The hurt will go away after a while.”
- for a randomized trial of chemotherapeutic agents, “The medicines may make me feel sick. I may have a belly ache. I may have headaches. If I feel sick, I should tell my mom or dad.”

Describe the principal benefits of the study, e.g.
for research not offering the prospect of direct medical benefit, “Being in this study will not help me. What scientists learn may help children in the future.”

for research offering the prospect of direct medical benefit, “Being in this study may help me with my_______ [asthma, cancer, etc.]. What scientists learn may also help children [with asthma, cancer etc.] in the future.
I can say “no” and scientist will not be mad at me. If I say “yes” now, I can change my mind later.

I can talk to my parents and the scientist about the study.

Once I turn 18 years old, I may be contacted by someone on the study team regarding my continued participation on this study.

___ YES, I want to be in the study.

___ NO, I do not want to be in the study.

__________________________________________
Name of Child

__________________________________________  ______________
Signature            Date

__________________________________________
Name of Investigator Conducting Assent Interview

__________________________________________  ______________
Signature            Date