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 <u>briefly</u> 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