***[This sample assent language is provided as guidance only; there is no requirement that investigators use this exact format. Investigators who have a template they prefer that includes any required elements are welcome to use it.***

***In general, assent forms or scripts need to convey the basic and important elements of the research in a way that the subjects (in most cases, children) can best understand. The language that you use in your form or script needs to be very appropriate to the targeted study population. If you design a form to be read by children ages 10 – 15, then the readability level should be such that the 10-year-olds can understand. Older children (e.g. ages 13 and older) can often read and sign the consent form along with their parents; provided the form is at a level they can understand. Please refer to the IRB website*** [***http://www.msudenver.edu/irb/***](http://www.msudenver.edu/irb/) ***for more detailed guidance on consent and assent.***

***The sample language provided here must be adapted to your own project and to your targeted population. Prior to submission to the IRB, any guidance language must be removed. Only ‘clean’ final versions of assent documents will be accepted for review. If you have any questions on how to adapt a template to your study, please contact the HSPP.]***

Children 7 years of age or younger: *[For many studies with young children assent is not appropriate or required. However, when possible, a very brief and simple explanation of the research procedures can be provided verbally, so children know who you are and what they are being asked to do.]*

“Hi, I’m ***[insert name here]***, and I’m going to school too. I am learning about children like you. In your class today, we are going to play a game about counting. We will count beans and put them in special boxes. I want to see if using the boxes helps you learn to count. Do you want to play the counting game?”

“Hi, I’m ***[insert name here]***, and I’m going to school too. I’d like to talk with you about reading a book. Your mom/dad is going to read you a book, and then I’m going to ask you some questions about the story. There are no right or wrong answers because this isn’t a test. I just want to learn more about the story.”

Children 8 to 12 years of age: *[Children in this age group can often understand more details about the research and can read a simple assent form – or have it read to them. The following template language may be used to develop a written assent form or a verbal script.]*

***Title of research study: [Insert title of research study here with protocol number, if applicable.]***

***Investigator: [insert name of principal investigator]***

We want to tell you about something we are doing called a research study. A research study is a way to learn more about people. We are doing a research study to learn more about ***[state the purpose in simple language]***. After we talk about it, you can decide if you want to be in this study or not.

If you decide that you want to be part of this study, we will ask you to ***[describe the research procedures or task here in a way that the children can understand, including the estimated time involved. For some studies, it may be important to inform the child if their parent or teacher will be present during the study procedures]***.

There are some things about this study you should know. These are ***[describe any risks, discomforts, timing of activities, etc. If there are any risks in this study (especially physical, psychological, or emotional risks) please explain what the researchers are doing to minimize these risks in a way the child can understand. For studies that involve questions or assessments, it may be important to convey to children that they are not being tested in a way that will make them uncomfortable or feel pressured. For example:]*** The questions we will ask are only about what you think. There are no right or wrong answers because this is not a test.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you or to others. We think these benefits might be ***[provide a simple description here]***.

***[If there are alternatives to the research:]*** If you do not want to be in this research study, we will tell you what other kinds of ***[treatments, lessons, activities, etc.]*** there are for you.

When we are finished with this study we will write a report about what was learned. This report will not include your name, so no one will know that you were in the study.

You do not have to be in this study if you do not want to be. It’s up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don’t want to be in the study or if change your mind later and stop. Your parents know about the study too.

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

**Assent: *[For some studies children may feel more engaged in the process if they sign a form; but, more importantly, documenting assent requires that the researcher certifies that the child was given the information and has verbally agreed to participate. The assent process, and documentation of assent, is highly variable and depends on the context of the study and the target population. Please modify according to the needs of your research.]***

Yes, I will be in this research study.

|  |
| --- |
|  |
| Printed name of child |
|  |
| Signature of the Child |

***[The following block can be added if you will document agreement of children on an assent form.***

***Alternatively, assent may be documented on the parent/guardian consent form.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |