# **Text Description automatically generatedAssent Form Templates (see ethics handbook for more information)**

**Children 15 years of age and older** are generally expected to give assent by signing the consent form used by their parents.  However, if an investigator believes an assent form using simpler language is a better fit for a potential participant in this age group because of the complexity of the study or the nature of the study population, one may be used.

# **Oral assent for very young children (ages 7 and under)**

Hi. My name is *[insert name]*. I am here today because I want to find out why/how kids with *[describe inclusion criteria in simple terms and a short description of the purpose of the study].*

Your Mom/Dad/Guardian has said yes to let me ask you some questions.

If you are willing to answer my questions, *[Insert a few (1-3) sentences explaining what is involved in participation]* (e.g., we are going to play a bunch of quick computer games/do some puzzles/read some stories/I’m going to ask you some questions). Some kids who answer these questions find them interesting, but sometimes they find them a bit hard/boring, but that’s ok, just try your best.

**[If the research is personal/sensitive]** I am going to keep everything you say/do here private. Only you and I will know what you do/say here today. I’m not going to tell your parents/teachers.

If you don’t want to answer my questions, that’s ok. I won’t mind. Even if you say yes, but change your mind later, just let me know and we can take a break or stop for good and it isn’t a problem.

Do you have any questions?

Do you want to try to answer some questions?

**Researcher attestation:**

I have explained this research study with \_\_\_\_\_\_\_\_\_\_\_\_\_\_ using understandable and appropriate language. They agreed to participate in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Researcher Signature Date

# **Younger child assent (approximately ages 7-10)**

Title of Study:

Principal Investigator(s): Phone Number(s):

Study Coordinator: Phone Number(s):

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about *[insert topic and describe goals in simple language].*You are being asked to join the study because *[insert name of condition or other reason(s) for inclusion].*

If you agree to join this study, you will be asked to *[describe procedures, (e.g., questionnaires, activities) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child].*

*Describe possible risks (e.g., discomforts) in simple language.*

**Will any part of the study hurt?** *(describe risks and discomforts using terms a child would know and understand; take into account a child’s fears)*

*Use any of the following statements that are appropriate:*

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

We expect that the study will help you by *[describe how].*

We may learn something that will help other children with *[insert name of condition or topic under investigation]*some day.

This study will help us learn more about *[topic under investigation].*

You do not have to join this study. It is 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 you join the study and change your mind later and stop.

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.

If you have any questions about this study, please feel free to contact *[Insert Study Contact name and contact #]*

* Yes, I will be in this research study.
* No, I don’t want to do this.

Child’s name Signature Date

Person obtaining Assent Signature Date

**If oral assent was obtained:**

I have discussed this research study with \_\_\_\_\_\_\_\_\_\_ using language which is understandable and appropriate for the participant.  I believe that I have fully informed them of the nature of the study and its possible risks and benefits.  I believe the participant understood this explanation and assent to participate in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Researcher Signature Date

# **Older Child Assent (approximately ages 11 – 14)**

**Title of Study:**

**Principal Investigator(s): Phone Number(s):**

**Study Coordinator: Phone Number(s):**

**What is a research study?**

A research study is a way to find out new information about something.  Children do not need to be in a research study if they don’t want to.

**Why are you being asked to be part of this research study?**

You are being asked to take part in this research study because we are trying to learn more about *(Insert name of what is studied here).* We are asking you to be in the study because *(state why the child is being asked to participate).* About *(enter #)* children will be in this study.

**If you join the study what will happen to you?** *(describe what takes place from the child’s point of view)*

We want to tell you about some things that will happen to you if you are in this study. EXAMPLES BELOW

* You will be in the study for *(insert duration of participation).*
* We will use a needle to take some blood from your arm *(#)* times.
* We will need you to take *(name of procedure)* that will last *(duration).* This is *(a simple explanation of what will happen).* Your *(mother/father/other)* can be *(location).*
* We will ask you to sit with us and *(talk about some things/look at some pictures)*.  It will take about 1 hour to do this
* We will ask you to answer some questions about *X*.

**Will any part of the study hurt?** *(describe risks and discomforts using terms a child would know and understand; take into account a child’s fears)*

**Will the study help you?** *(Describe any benefits to the child from participation in the research or if there are none omit this section).*

**Will the study help others?** *(Describe any benefits to society from the research.)*

This study might find out things that will help other children with *(insert name of condition being studied)* some day.

**What do you get for being in the study?**

You *(and your parents)* will get *(enter amount or item)* for *(each visit/entire study).*

**Do you have to be in the study?**

You do not have to be in the study.  It’s up to you. No one will be upset if you don’t want to do this study.  If you join the study, you can change your mind and stop being part of it at any time.  All you have to do is tell us.  It’s okay, the researchers and your parents won’t be upset.

**What choices do you have if you say no to this study?**

There are other ways to help your *(insert name of condition being studied)* if you don’t want to be in this study.  Examples are …….

This study is voluntary, so if you don’t want to do it (*nothing else will change)(there are no other choices).*

**Do your parents know about this study?**

This study was explained to your parents and they said that we could ask you if you want to be in it.  You can talk this over with them before you decide.

**Who will see the information collected about you?**

The information collected about you during this study will be kept safely locked up.  Nobody will know it except the people doing the research.

The study information about you *(will, will not)* be given to your parents *(or teachers).* The researchers will not tell your friends or anyone else.

**What if you have any questions?**

You can ask any questions that you may have about the study.  If you have a question later that you didn’t think of now, either you can call or have your parents call *(insert study telephone number)*.

**Other information about the study.**

* If you decide to be in the study, please write your name below.
* You will be given a copy of this paper to keep.
* Yes, I will be in this research study.
* No, I don’t want to do this.

Child’s name Signature Date

Person obtaining Assent Signature Date

**If oral assent was obtained:**

I have discussed this research study with \_\_\_\_\_\_\_\_\_\_ using language which is understandable and appropriate for the participant.  I believe that I have fully informed them of the nature of the study and its possible risks and benefits.  I believe the participant understood this explanation and assent to participate in this study.

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Researcher Signature Date