

Assent Form Template for Children Ages 7-11 Instructions

Notes to Researchers:

- This assent form template is designed for children ages 7-11. This age group should be fully informed about the research, using language appropriate to their age and maturity.
- This template should be used to assist study teams in the design of their research assent forms for children. It is important that study teams adapt their own assent forms to adequately describe their particular study.
- Update the footer in the bottom to “Version 1” with the current date. If revisions are made to this form after approval, update the version and date before submitting for IRB approval.
- Language in red should be replaced with language specific to your study.
- When writing the assent document, remember the following:
 - Language should be at a level appropriate to the child’s age and development.
 - An assent form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child’s willing cooperation in the study.
 - The assent form should be written in second person with complete grammatically correct sentences. Scientific jargon and legalese is not appropriate.
 - Use reader-friendly formatting so that your document looks easy to read. Use 1” margins and include sufficient white space between headings and paragraphs. Use subheadings, bulleted lists, tables, etc. to improve readability. Use clean, black, minimum 12 point font.
- Assent expires when a child turns 18 years of age. At that time, the participant must be re-consented by signing the IRB approved adult consent for the research study.

Delete this instruction page prior to IRB submission.

TEMPLATE ON FOLLOWING PAGE

**UNIVERSITY OF SOUTH ALABAMA
ASSENT FORM FOR RESEARCH**

For children 7-11 years old

[Insert title of the study]

**[Name of Principal Investigator]
[Contact information of PI]**

Why are we meeting with you?

We want to talk to you about being in a research study. Research studies help us understand how things work or help us find better ways to treat people. This form will tell you more about a research study we are doing. After we tell you about it, we will ask if you want to be in the study or not. It is your choice.

Important things to know

Even if your parent/guardian agrees that you can be in this research, you still get to decide.

- You can say “Yes” or you can say “No,” it is up to you.
- If you say no, no one will be upset with you. If you say yes, you can still change your mind later and stop being in the research.
- You can take your time and ask any questions.

Why are we doing this study?

In this study, we want to find out more about **[describe the purpose of the study and why they are included, preferably in 1-2 sentences]**.

What happens in this research study?

If you agree to be in the research, you will be asked to **[describe the procedures in age appropriate, simple terms and be clear how long each procedure and each study visit is expected to take. Use of lists, bullet points, tables, or diagrams to clearly describe each procedure is strongly encouraged]**.

Could anything bad happen in this research?

[Insert a simple description of the risks, for example:

Some of the questions may be hard to answer and you may not like answering them. If there is a question you do not want to answer, it is ok not to answer and skip it.

OR

The medicine we give you may make you feel sick.

OR

The stick from the needle to draw your blood will hurt, but the hurt will go away after a while.]

We will try our best to keep your health and personal information private, but we cannot promise it.

Can this research help you or other people?

This research may or may not help you. We hope that [describe benefits].

OR

This research may not help you, but what we learn from the study may help other people in the future.

Will you be paid for this research?

You will not be paid to be in this research study.

OR

You will be paid if you do this research with [type (e.g., a gift card, cash, check) total amount of compensation, and when payment will be made].

Do you have any questions?

You can ask questions anytime. You can ask now. You can ask later. You can talk to me or you can talk to the study doctor or other study team members.

Do you have to be in this study?

You do not have to be in this study. No one will be upset if you don't want to do this. Or, you can say yes now and change your mind later. It's up to you. [If medical research: Your doctors will still take care of you even if you decide not to be in this research study.]

You can take your time to decide. You can talk to your parent or guardian before you decide.

Minor Participant Signature

If you want to be in this study, please sign your name below. If you sign here, it means:

- you agree to participate in this research
- you can ask questions any time
- you can change your mind later if you do not want to be in this research

Printed Name of participant:

Signature of participant:

Date _____

Person Obtaining Consent:

I have reviewed this assent form with the potential participant. I confirm they were given an opportunity to ask questions about the study and all questions have been answered. A copy of this ICF will be provided to the participant.

Printed Name of person obtaining consent:

Signature of person obtaining consent:

Date _____