

TEMPLATE ASSENT FOR CHILDREN AGE 7-12

**Introduction**

**This template should be used for research projects involving children aged 7-12. A separate assent document is required for children aged 13-18.**

For more information on the requirements for assent, see the [Creighton University Human Research Protection Program Policy Manual](#), Section 4.4, "Research Involving Children."

**Instructions**

Guidance on what should be included is in red. **All red text should be removed** in the form submitted to the IRB for review.

You must use the black text exactly as written; you may not edit or change it.

- Font must be at least 12 point. If enrolling older adults, consider using larger print.
- Page numbers are required and must be on the bottom of the page.
- PI name and the version of the document (this can be a date or a number) must be on the first page and in the header of all following pages.
- If applicable, participant ID should be in the header.
- Bottom margin must be at least 1 inch.
- Use language that the average person is likely to understand.
  - Written no higher than sixth grade- reading level.
  - Define any technical terms and/or acronyms.
- Write using second person (i.e., participant addressed as "you" and investigators as "I/we").

Do not include this page in your page numbers. **This page can be deleted.**

**Example First Page:**

**Protocol Title:** Research on Research

**IRB Project Number:** 2000000-02

**Protocol Version:** 12/15/2024 or 02

**Principal Investigator Name:** Dr. Research

**Principal Investigator Department:** Research and Compliance

**Example Header:**

PRINCIPAL INVESTIGATOR: Dr. Research  
VERSION: 02

Or

PRINCIPAL INVESTIGATOR: Dr. Research  
VERSION: 12/15/2024



## ASSENT FOR CHILDREN AGE 7-12

Protocol Title:

IRB Project Number:

Assent Version:

**Sponsor:**

Principal Investigator's Name:

Principal Investigator's Department:

Principal Investigator's Telephone Number:

**Research Investigators' Names and Departments:**

**Research Coordinators' Names and Departments:**

***Only personnel listed above may be involved in the consent process.***

**24-Hour Telephone Number:**

***Must have a 24-hour number listed if the research has more than minimal risks.***

### **Study Invitation**

We want to tell you about a research study we are doing and see if you want to take part in it. A research study is a way to learn more out about something.

It is okay to ask questions about what we are telling you. If you don't understand something, just ask us. We want you to ask questions now and you can say no at any time. You will not be treated any differently if you say no.

For you to be in this study, both you and your parent (or guardian) must agree to you being in it. We will ask your parents or legal guardian if it is OK for you to be in this study.

### **What is the study about?**

We are working to [find out/learn more about – i.e. provide a simple explanation of the purpose of study].

You are being asked to be in this research study because [insert simple/layperson name of medical condition or other reasons for inclusion].

If you decide to be in this study and your parent (or guardian) says yes, this is what will happen:

[Summarize what is expected of participants. This does not have to include everything in the parents' permission form. Focus on procedures that are important to the child, from a child's viewpoint].

- We will have you [explain].
- We will ask you to [explain].
- The research will take [insert estimated total amount of time].

- This will take [XX] visits that each last about [amount of time per visit].

**Can anything good happen to me?**

If you decide to be in this study, [Describe possible direct benefits, such as “some good things might happen to you, but we don’t know for sure that these things will happen” and describe the possible direct benefits; otherwise, state something such as, “you will not be helped by the study, but it may help us learn something that will help other children with [insert name of subject matter of study] someday.”].

**Can anything bad happen to me?**

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

[Describe risks – e.g., painful procedures, other discomforts, things that take a long time]. You can stop at any time if you want to.

You don’t have to be in this study if you don’t want to. Nobody will be mad at you if you don’t want to be in the study. You can say okay now, and you can change your mind later. Just tell the researcher or your parent (or guardian) if you want to stop at any time. [Insert the following, if appropriate: Your doctor will still take care of you if you don’t want to be in the study.]

**Contact Information**

If you have questions or are worried about anything happening in this study, you can talk to [insert study team member and contact information].

### ***Bill of Rights for Research Participants***

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.
3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
4. To be told about the reasonably foreseeable risks of being in the study.
5. To be told about the possible benefits of being in the study.
6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
7. To be told who will have access to information collected about you and how your confidentiality will be protected.
8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research participant.
9. If the study involves treatment or therapy:
  - a. To be told about the other non-research treatment choices you have.
  - b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.