

This template has been developed in an effort to help researchers navigate the process of writing a complete assent document that will include required information, utilize an accepted format, and use suggested language approved by the Institutional Review Board (IRB).

# INSTRUCTIONS FOR DEVELOPING AN ASSENT DOCUMENT

**[TEXT FOUND THROUGHOUT THIS DOCUMENT IN BOLDFACE AND BRACKETS OFFERS GUIDANCE AND SUGGESTIONS. DELETE THIS TEXT AND REPLACE IT WITH THE APPROPRIATE WORDING FOR YOUR PROJECT.]**

The Assent document is to be used when participants who, by age or circumstance, are not able to give legally effective informed consent. When legally effective informed consent cannot be obtained, the investigator should obtain the “assent” of the minor or cognitively impaired participant. This form documents the minor’s or cognitively impaired participant’s affirmative agreement, or assent, to participate in a research project. The investigator should respect the decision of a minor or cognitively impaired participant to *not* participate, even when the parent or legally authorized representative is willing to sign the Informed Consent document.

 In the case of minor participants, the IRB recommends that this form be used with children who are in the 7 – 12 age range. If properly written at an age appropriate reading level, an informed consent document can be used for participants in the 13 – 17 age range; otherwise, an assent document must be used to enhance their comprehension or if the study involves complicated procedures.



**ASSENT DOCUMENT**

Project Title: **[Title]**

Principal Investigator: **[Name and department]**

Co-Investigator(s): **[Name and department of individuals responsible for the conduct of this project]**

We are doing a research study. A research study is a special way to find out about something. We are trying to find out **[purpose of study in simple language]**.

This form is about the study, so you can learn about the study and decide if you want to be in the study or not. You can ask any questions. After all of your questions have been answered, you can decide if you want to be in this study or not.

 If you decide that you want to be in this study, we will ask you to do **[one/several]** things. **[Describe procedures simply, including how many contacts.]**

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.]**

If you decide to be in this study, some good things might happen to you. **[Describe possible direct benefits.]** But we don’t know for sure that these things will happen. We might also find out things that will help other children some day.

When we are done with the study, we will write a report about what we found out. We won’t use your name in the report.

You don’t have to be in this study. It’s up to you. If you say okay now, but you want to stop later, that’s okay too. All you have to do is tell us.

If you want to be in this study, please sign your name.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, want to be in this research study.

(Print your name here)

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Signature/Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_