

General Guidelines

[Title of your Institute]

Informed Assent Form (Respondents under age 18)

[Informed assent form should be on the Institute's letterhead]

Assent refers to agreeing or approving after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years, who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with the informed consent of the parent.

Obtaining Informed Assent from Children or Minors Parents, legal guardians, or a legally authorized official must sign consent forms permitting children or minors to participate in research projects. In addition, children and minors are required to sign an Assent Form.

The content of an assent form for children participating in research should be tailored to their age and understanding. It should be written in simple, clear language that aligns with their cognitive, social, and emotional development. Here's a breakdown of key points to include:

Key components to include are:

- 1. Explanation of the Study (Benefit & Purpose):**
 - a. briefly explain the research project and how it might benefit children like them In a child-friendly way. Mention the activities involved in the study, including any potential discomfort the child might experience.
- 2. Study Procedures and Potential Discomfort:**
 - a. Describe the activities involved in the study, using simple language and avoiding medical jargon.
 - b. Mention any potential discomfort the child might experience and assure them it will be minimized.
- 3. Right to Ask Questions and Contact Information:**
 - a. Emphasize that the child can ask questions about the research at any time.
 - b. Provide contact information for a person the child can reach with questions or concerns (e.g., researcher, parent liaison).
- 4. Voluntary Participation and Confidentiality:**
 - a. Clearly state that the child's participation is voluntary and they can refuse to participate or withdraw at any point without impacting their treatment or care..
 - b. Assure them that refusing will not affect their treatment or care at the center.
- 5. Consent and Contact Information:**
 - a. Provide contact information for a person the child can reach with questions or concerns.

Sample:

[*Project Title:*]

My name is [*Your Name*], and I'm here to talk to you about a study we're doing about [*Project Title and Brief description of the study in child-friendly language*].

Your parent(s)/guardian(s) have already given their permission for you to participate, but it's completely up to you if you want to be part of it [*explain the voluntary nature of participation and right not to participate and withdraw*]

You may feel some inconvenience because of the time and effort to be a participant. You may also find some questions that we ask to be upsetting or may feel embarrassed to answer them [*mention any potential discomfort in a gentle way*].

You do not have to respond to any question that makes you uncomfortable and you may stop the interview at any time and nothing will happen. There are no direct benefits to participating in the study, although you will help us understand what children like you want or need.

Your participation is entirely voluntary and you can stop the interview at any point of time even after having agreed to participate. If you decide not to participate it will not affect any benefits to which you are entitled. I want to assure you that the information you provide during the study will be kept private and confidential.

If you have any question, please feel free to ask them to me. Or you can also contact the Project PI on the following address. [*Address questions of the child regarding the survey if any*]

Principal Investigator: [Name, Affiliation, Office, Mobile, Email Address]

[Principal Investigator and Contact Information]

Do you agree to participate in this survey? [*Verification of child's consent*]

Tick the answer:

1. *Consent given along with signature/ thumb impression*
2. *Consent given but without signature/thumb impression*
3. *Consent Refused*

[Interviewer's **Declaration**]

I confirm that the individual has given consent freely. *I have taken consent from parents (assent from in case of minor) before the interview*

Interviewer's Name and signature: _____ Date: ____/____/____
