Eastern Illinois University

Institutional Review Board for Review of Research Involving Human Subjects

Guidelines for Seeking and Obtaining Assent from Minors and Decisionally-Impaired Adults

When children (age 0 through 17) or decisionally impaired adults are the subjects of research, they have the right to decide if they wish to participate as a subject in research. Assent is the process of providing details of a study in a developmentally appropriate way, and obtaining a subject’s verbal or written permission to participate.

Assent can be solicited from a minor or decisionally impaired adult **only** **after** a parent or guardian has provided informed consent.

* A child **can decline** to participate in research, even if the parent or guardian consented to it.
* A child **cannot provide assent** if the parent or guardian did not consent to participation.

**Assent Procedural Guidelines**

When working with minors or decisionally impaired persons, the assent process should consider their development and cognitive understanding. It is important to consider the participant’s ability to read, speak, and comprehend information.

Depending on the participant’s development:

* Assent Information can be provided verbally or in writing, and
* Permission to participate (assent) can be obtained verbally or in writing.

For instance, it is developmentally appropriate to verbally explain the details of a study and obtain assent verbally from a young child, whereas it is developmentally appropriate to have an adolescent read the details of a study and obtain written assent.

The following procedural guidelines are recommended for typically developing children:

Children through age 4:

* Information is provided verbally
* Assent can be obtained verbally or via non-verbal communication (e.g. nodding)

Children ages 5 through 8:

* Information is provided verbally
* Assent can be obtained verbally or in writing

Children ages 9 through 13:

* Information can be provided verbally or in writing
* Assent can be obtained verbally or in writing

Children ages 14 through 17:

* Information is provided in writing
* Assent is obtained in writing

Whether study details and assent are provided and obtained verbally or in writing, all participants must be afforded the opportunity to ask questions.

**Appropriate Assent Language:**

Study details need to be communicated using language and wording that considers the potential participant’s ability to understand the information, sustain attention, and focus on what is being communicated. Subjects will need to be asked to participate in a way that is clear to them. Considering this, a shorter, briefer explanation is commonly used with young children and a longer, more detailed explanation is more common with older children. The following phrasing guidelines are recommended for typically-developing children.

Children through age 4:

The investigator would ask a potential participant if they would like to participate in the activity. The investigator monitors the participant(s) for signs of distress and informs them they can stop if they want to.

For example:

“*Would you like do some exercises and then try make some baskets?*”

“*Can I talk with you about your favorite snacks?*”

Children ages 5 through 8:

The investigator informs the participant that research is taking place, what they can expect to happen and what will be expected of them. The investigator asks the participant if they want to participate and inform the participant they do not have to participate and can stop at any time. Risks, confidentiality, and safety precautions should be addressed when appropriate.

For example:

“*I want to find out if doing some exercise will help you with basketball. We will do some easy exercises that I will teach to you. Then, we will practice basketball skills. You don’t have to you don’t want to. If you play and then want to quit that’s ok too. No one will be upset with you.*

*Sometimes people can get hurt a little bit when playing sports. Please let me know right away if you get hurt while we are playing or exercising.*

*Do you have any questions for me?*

*Would you like to practice basketball skills and learn some exercises?*”

Children ages 9 through 13:

The investigator provides the following information to potential participants (verbally or in writing):

* Research is taking place
* What they can expect to happen and what will be expected of them if they participate
* Any potential risks and safety precautions in place, and to what extent their confidentiality will be maintained
* That they do not have to participate and can stop at any time with no consequence
* Who participants can contact if they have questions or concerns

The investigator then asks the subject if they want to participate.

For example:

“*I am studying exercises and want to find out if doing certain exercises will help with your basketball skills. Today we are going to practice basketball skills for 15 minutes. Tomorrow, we will do some exercises, then practice the same basketball skills to see if they are easier to do after the exercises.*

*If you don’t want to do these activities you don’t have to. No one will be upset with you. You can also quit any time and that’s ok too. This is for fun, and I won’t be grading you. I will be taking notes but won’t be using anyone’s name in my report.*

*Sometimes people can get hurt when playing sports. If this happens to you when we are playing basketball or exercising, please let me know right away so I can help you. If you got hurt or have been sick this past week please let me know.*

*My instructor at Eastern Illinois University is helping me with this study. Her name is Dr. Jane Doe. Your parents or guardians know about this and gave me permission to ask if you want to participate. If you have any questions you can ask me or your parents or guardians. You can also ask Dr. Doe. Her e-mail is at the bottom of this letter.*

*Please sign your name on the line below if you would like to participate in this study.*”

Children ages 14 through 17:

Potential subjects are capable of processing all informed consent information, however, language should be simplified and phrasing should be streamlined.

**Attach full text of the assent document (or script if delivered verbally) to the application.**