ILLINOIS
Office for the Protection of Research Subjects

Research Guidance Document

ASSENT

Definitions

The principle of respect for persons is based on the understanding that individuals are autonomous agents. The choices made by an autonomous person should be respected. Under the usual conditions of research, this is accomplished by soliciting the informed consent of the prospective research participant. In the case of an adult with diminished decision-making capacity or non-autonomous child, applying the principle of respect for persons may be problematic. Therefore, permission of either the parent or legally authorized representative is required. However, individuals capable of some degree of understanding (generally, a child of 7 or older, or an adult with diminished decision-making capacity) should participate in research only if they assent.

Assent means a participant's affirmative agreement to participate in research. Mere failure to object should not, when absent affirmative agreement, be construed as assent. When assent is required by the IRB, the decision of the individual assenting is binding.

Federal Research Regulations

As outlined in 45 CFR 46 and 21 CFR 50, Subpart D (Additional Safeguards for Children Involved in Research), the IRB must determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent.

Although there are no federal regulations governing assent for adults with diminished decision-making capacity, it is the policy of the University of Illinois Urbana-Champaign IRB to find that adequate provisions are made for soliciting the assent of the participant, when, in the judgment of the IRB, the participant is capable of providing assent.

Description

Assent for Children

Investigators must provide the IRB with information regarding the plan to obtain assent from children involved in the research. Because the IRB must evaluate the age, maturity and psychological state of the children, it is important for the investigator to provide as much information about the children who will be recruited. Generally, the IRB requires assent from children 7 or older but this may vary depending on other factors. Once the IRB has enough information about the assent process, the IRB determines whether assent is a requirement of all children, some of the children or none of the children.

If assent is NOT a requirement for some or all children, the IRB must make one (or more) of the following findings:

- The children are not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children is so limited that they cannot be reasonably consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
- The assent process is entirely waived consistent with the provisions for waiver of consent contained in 45 CFR 46.116.

Examples:

1. A study involves teenagers from ages 12-16 years old. The teenagers the researcher plans to recruit appear to be of appropriate age and maturity and appear to be in an appropriate psychological state to assent to be in research. The IRB would likely determine assent is a requirement of all of the children.

2. A study involves infants from ages 3 months to 9 months old. The IRB determines assent is not required or any of the children. The IRB would likely determine the children are not capable of providing assent based on the age of the children.
3. A study involves children from ages 1-10 years old. It is clear that a toddler would be unable to assent to the procedures involved. The IRB determines that the assent is required of only some of the children. For those under the age of 7, the IRB would likely determine the children are not capable of providing assent based on age of the children. For those 7 or older, the IRB would generally require assent be obtained.
4. A study involves children from ages 9-17 years old. The researcher plans to recruit children that are cognitively impaired due to traumatic brain injury. The IRB may determine assent is not required of any of the children because the capability of the children is so limited that they cannot be reasonably consulted.

Assent for Adults with Diminished Decision-Making Capacity
The investigator should consider an assent process (accompanied by consent from a legal authorized representative) for persons with diminished decision-making capacity. Additional considerations for adults with diminished decision-making capacity such as:

- Should a re-assenting or re-consenting process take place throughout the study to ensure voluntary participation?
- For those participants who may recover an adequate amount of decision-making capacity, are there plans to obtain full informed consent from the participant?

For more information, please see the Investigator Guidance Series: Research Involving Individuals with Decisional Impairment found on the IRB website.

Documentation of Assent
Once the assent process has been completed, an assent document will typically be used to document assent. If the investigator plans to document assent using another method or does not plan to document the assent process, the IRB must approve of such a plan.

Additional Considerations

What is required when a child reaches the legal age of consent?
Informed consent is an on-going process throughout the duration of a research project. When a child who was enrolled in research with parental/guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the investigator should seek and obtain legally effective informed consent for the now-adult participant for any ongoing interactions or interventions with the participants unless the IRB determines that the requirements for obtaining informed consent can be waived. Prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult participant.

If the study does not have an IRB-approved consent document for adult participants, an amendment is required to obtain approval of the consent document prior to use.

Points to Address

New Study Application:	1. **Consent Process page:** The assent process and plan for documentation of assent must be described in detail. If assent is to be used with individuals with decisional impairment, the investigator should review the applicable Investigator Guidance Series document(s) for additional points to consider.

References & Links

Research Guidance Document

IRB SOP 704: Assent	To be updated
Assent Models	*To be updated*
Investigator Guidance Series: Research Involving Individuals with Decisional Impairment	*To be updated*