Assent of Children

Modified: January 2017

Background:

According to the Common Rule, assent is the affirmative agreement of the child to participate in the research. Mere failure to object does not constitute assent.

While it is the responsibility of the IRB to evaluate the research and determine if assent will be obtained from none, some, or all of the child subjects, the investigator must provide adequate information for the IRB to make that decision. The IRB will take the age, maturity, degree of literacy, and psychological state of the children involved into account when making this determination. This judgment may be made for all children to be involved in given research study, or for each child, as the IRB deems appropriate.

Q: In general, when is assent recommended?

1. Assent is not recommended in children less than 7 years old, irrespective of risk or benefit;
2. Assent is recommended, but not required for children between the ages of 7 and 14, irrespective of the risk or benefit;
3. Assent is required* for children over the age of 14, irrespective of the risk or benefit.
   a. Unless there is an incapacity
   b. If there is potential for direct benefit, and there is a conflict between the subject and LAR, then an Ethics Committee review is required*.

*Required: this is the preferred recommendation. However, the IRB can opt not to require assent depending on the project or situation.

Q: Is assent every required by the IRB?

Yes. In studies where there is no prospect of direct benefit to the children, the children are over the age of 7, and the IRB determines that the subject matter, the length of participation, or other similar issues results in the IRB mandating assent of the children as a condition of enrollment. The IRB will determine if any information other than the UF IRB Assent Template is needed to provide to potential children study subjects.

Q: When is assent not required?

The assent of children to participate in research is to be obtained based on the above question, except in the following circumstances:

1. The children are not capable of providing assent based on age, maturity, or psychological state
2. The capability of some or all of the children is so limited that they cannot reasonably be consulted
3. The intervention or procedure involved in the research holds out a prospect of direct benefit to the health or well-being of the children and is available only in the context of the research
4. Assent can be waived using the criteria for waiver (or alteration) of informed consent found in 45 CFR 46.116.
Q: What are the responsibilities of the person obtaining assent?

The person obtaining assent must:

1. Provide an explanation of the study, at least as much information as the child is capable of understanding, in terms that the child can understand.
2. If the IRB requires the child’s signature, ensure the child signs the informed consent document on the appropriate signature line.
3. Document in the study record if assent was requested, and the potential subject refused.
4. Document if there was an incapacity and thus assent was not requested.

Q: What should the assent process include?

The assent process must include an explanation of the research procedures using words and visual aids that are appropriate to the child's age, experience, maturity, and condition. In addition, the explanation must include a discussion of any discomforts and inconveniences the child may experience during participation.

Q: Is an additional assent form required to document assent?

No. The current template assent [Link to template language] statement may be appended to the signature section of the consent form.

Q: Is a written signature of assent ever required?

Yes. If the IRB determines that assent is required as a condition of the child’s involvement in the study (see questions above), then written documentation of assent may be required. If required, the signature must occur on the UF IRB Assent Template on the signature page of the Consent Form. The IRB may decide on the documentation of assent in other formats on a case-by-case basis.

If assent of the child participant is recommended but not required, then if assent is obtained, documentation of the assent should be made on the UF IRB Assent Signature Template. If the child participant provides verbal assent, the study team should document the child’s verbal assent in the research record to include the date and time verbal assent was obtained, any questions or concerns the child expressed during the process, the resolution of those questions and concerns and who obtained the verbal assent from the child.

For more information, see the OHRP Research with Children FAQs [link to: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html#]