

Assent of a Child

“Assent” means a child’s affirmative agreement to participate in research. A child’s failure to object *should not*, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b)).

When assenting children:

- Different assent documents may be required when a study involves several age groups.
- *A Parent Consent Form must be signed by a parent or guardian prior to obtaining their child’s assent.* Parent Consent Forms must contain all of the required elements of a standard informed consent form with a modified signature section. Refer to the Parent Consent Form model.
- All assents must be documented and include the signature of the witness to the assent process.

The following breaks out how the assent should be handled for children of different ages.

Ages 2-6:

Children under 7 years of age are assumed to be unable to give assent. A Parent Consent Form is required. Document the reason for waiver of the assent in the IRB application.

Ages 7-12:

Children between the ages of 7 and 12 must have a parent sign a Parent Consent Form and the child must sign the assent form.

The request for assent should include: (1) a general description of the purpose of the study; (2) why the child is being asked to participate in the study; (3) a brief description of the experimental tasks; (4) an assurance that the child's participation is voluntary and that he/she may withdraw from the study at any point; and (5) an offer to answer questions. Refer to the model template.

Ages 13- 17:

Children between the ages of 13 and 17 must have a parent sign a Parent Consent Form and the child must sign the assent form.

A modified Informed Consent for Adults template can be used incorporating language appropriate to the child's level of comprehension. Refer to the model template.

Please use the assent model that corresponds to your study population; modify the language based on the age of the child. The models are for guidance and *should not be used verbatim*. The language used should be age appropriate for the study and sections highlighted in yellow should be modified to fit your study.