

Assent of Children

Requirements for Permission and Assent

The regulations at [45 CFR 46.408](#) and [21 CFR 50.55](#) include requirements for obtaining or waiving parental permission and assent of child participants.

408(a) defines when assent of children will be required and when it can be waived. The IRB can waive the requirement of assent if either

- some or all of the children will not be capable;
- under some circumstances when the study holds out the prospect for direct benefit; or the research meets the same requirements as waiver of consent

408(b) allows that the IRB may find that the permission from one parent is sufficient for research approved under either 45 CFR 46.404 or 405 but requires that permission from both parents be obtained for research approved under either 45 CFR 46.406 or 407. Exceptions are allowed when one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

408(c) allows the IRB to waive parental permission when it is not a reasonable requirement for the research, provided that there is an alternative mechanism in place to protect the participants. This is most frequently invoked for research involving adolescents but might also apply to research involving younger children such as those who are abused or neglected. Assent may be a sufficient alternative mechanism for protection for teenagers but some other substitute for a parent (e.g. an advocate) will generally be required for younger children. This will also depend on the risk and complexity of the research.

408(d) the documentation requirements for parental permission are the same as for informed consent.

408(e) places the responsibility on the IRB to determine if and how assent is to be documented.

How should assent be obtained?

The abilities and needs of children vary. Investigators should describe the study and obtain assent in a manner appropriate for the individual child. As with obtaining consent from adult subjects, obtaining assent should be a discussion. The child's assent must be affirmative. Acquiescence is not evidence of assent.

45 CFR 46.402 Definitions

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction where the research will be conducted.

Assent means a child's affirmative agreement to participate in research. Acquiescence is not evidence of assent.

Permission means the agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

How should assent be documented?

COMIRB usually recommends documenting assent for subjects ages 7-12 through the use of a simplified assent form and documenting the assent for subjects ages 13-17 by asking the subjects to sign the consent form signed by their parent(s)/guardian(s). Hospital policies may also require that assent be documented in the electronic medical record.

What information should be included in an assent form?

An assent form need not include all the elements of consent. It should be written using simple, age-appropriate wording. The assent form must be understandable to the children that will be asked to read it. The assent form should state clearly that the child can choose to be in the study or not. The assent form should summarize the purpose of the research and the procedures, explain whether any of the study procedures will hurt, and explain whether the child may benefit from being in the study. The assent should also state that if the child decides to participate, they can change their mind later. A template assent form is available [here](#).

FDA assent exceptions

FDA regulations allow that the assent of children is not necessary if the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.

Other waivers of parental permission and assent

COMIRB may also waive the requirement for parental permission and/or assent for minimal risk research that qualifies for a waiver of consent.

Contact COMIRB

If you have any questions, please contact [COMIRB](#). We are happy to answer your questions and to schedule a meeting with you to discuss your study.

FAQ: Assent of Children

What if my study enrolls children ages 2 - 17 years; do I need to obtain assent from everyone?

The IRB expects that the investigator will submit a proposal describing which age groups will be able to provide assent and which will not. This should be based on the type and complexity of the research and the population being enrolled. It may be appropriate in some studies and for some age groups to obtain verbal assent and document that assent in the research records. Children too young to read and sign an assent form may be old enough to still have the research procedures explained to them in terms appropriate to their level of understanding and maturity. Researchers should describe their plans in the IRB application.

Should children be told how much money they will be paid?

Yes. If children are going to be paid for their participation, they should be told how much and the basis for payment. Researchers should base payment on the amount of time and effort required.