

Guide to Assent for Minors

Federal regulations require a number of special protections for minors (in Louisiana, persons under the age of 18).

45 CFR 46.408 states "the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. ... the IRB shall take into account the ages, maturity, and psychological state of the children involved." (The LSU IRB is likely to also take into account the nature of the study.)

Assent is a process in which the research is adequately explained, questions fully answered, and agreement to participate, if granted, is documented. In obtaining a minor's assent, at a minimum, the subject must have explained to him or her orally in age-appropriate terms what will happen to the individual, why it is being done (e.g., "to find out..."), any risks or discomfort expected, and any benefits to the individual or to others. Refusal to assent must be honored, no matter how irrational it may appear to be. Mere absence of dissent may not be regarded as assent.

LSU IRB policy regarding assent:

1. Assent will generally be required of children aged 6-18. However, the lower age limit may be modified in special circumstances.
2. It is recommended that assent be obtained in the presence of the parent when possible, unless there is evidence the parent will be inappropriately coercive of the child entering the study.
3. To document assent, a separate instrument - in addition to the parent or guardian's permission form - is usually required. The assent form should reflect in suitably simple terms what information has been conveyed to the minor subject in order to secure his/her agreement to participate in the study. However, in certain FAMILY studies, if it seems appropriate that the decision to participate be made jointly by parent(s) and child, parental permission and child's assent may be documented in the same form.
4. The assent form should record the age of the child and the date of signatures.
5. The assent form should be signed by a witness to the assent procedure (may be the parent/guardian or a third party). When a witness is used to assist in documenting assent, the witness should be present to attest to the entire consent process, not just to the child's final acquiescence. The child should sign the assent form if judged to be able to understand that signature represents a REVOCABLE agreement to participate in the research. Normally the child's signature would not be requested below age 8.
6. Original signed assent and parental permission documents must be kept in the investigator's records for at least 3 years after termination of the study.

Finally, the investigator(s) must pay attention to the fact that a young child may be unable to verbalize dissent or a wish to withdraw from the study, and so must be alert and responsive to the child's non-verbal cues. For instance, if a child physically resists a procedure, resistance should be considered an indication of dissent, and the investigator has an obligation to desist, unless he/she can establish that the child is willing to continue in spite of the evident discomfort. These considerations become imperative if there is no overriding benefit to the individual child.

In longitudinal studies, it may be appropriate to ask the subject to reaffirm assent at intervals.

Please contact us if you
have questions about this
guide.

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