

IRB Requirements for Obtaining Informed Consent from minors *Guidance for researchers*

Informed consent is designed to protect the rights of the participant and the investigator. In the event that the participant is a minor, an informed consent form (*see Template B of the IRB Submission form*) must be signed by the minor's custodial parent (parent who has primary custody of the minor recruited for the study) or legal guardian. In minimal risk research (expedited protocols), only one parent signature is required. And, to document that the minor is also agreeing to participate, assent must be obtained by the child and documented in writing (*see Template C, section XII. Witnessing and Signatures of the IRB form*).

Obtaining and documenting informed consent when conducting research with children is a more challenging process than obtaining informed consent with adults. The following (in blue) is taken from Xavier University's *Informed Consent Process*, as it provides good guidance on different types of consent/assent, depending on the age and abilities of the minors in question:

Minors or special adult populations who are being recruited as research subjects may be compromised in their ability to provide truly informed and voluntary consent and therefore require special safeguards to ensure that their rights are protected in the informed consent process.

- 1) **Children:** Obtaining permission to conduct research involving children (persons under age 18) requires special attention to the child's age, his/her ability to understand what is asked of him/her, and his/her relationship to parents/guardians. If research subjects are wards of the state, further safeguards are required as outlined in 45CFR46. In all cases, the investigator must demonstrate respect for the rights of the subject within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the child (see IRB Forms for Sample Child Assent Form).
 - a. **Parental Consent:** Parental permission or consent in writing is required for all minors under the age of 18 who participate in research except for emancipated minors.
 - b. **Adolescent's Written Assent:** From about junior high or middle school onward, a child's written assent is needed (in addition to parental consent), because children in this age group usually can read and comprehend a well-constructed assent form. However, the investigator should use supplementary verbal explanations whenever needed.
 - c. **Child's Assent:** For elementary school aged children, the investigator should obtain (in addition to parental consent) the child's assent to participate. The explanation to the child should contain elements of consent expressed in a form the child can understand. A conversational question-and-answer setting is often necessary to achieve this goal. In addition, the child's assent should be positive, that is, not merely lacking of dissent. If the child is old enough to render a signature, investigators are required to obtain a signed assent form.
 - d. **Very Young Child's Assent:** For children below school age (e.g., infants, toddlers, and preschoolers) the investigator should give explanations that match the level of understanding. In many instances, the children's nonresistant behavior may be interpreted as assent, but the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. **A verbal script must be submitted as part of the protocol.**