

**Armstrong Atlantic State University  
Consent/Assent Procedures for Minors (Page 1 of 2)**

Research involving children is governed by the Code of Federal Regulations 45 CFR 46:401-409 (48 Federal Register 9818, March 8, 1983).

Legally, children cannot give consent on their own behalf. The consent of their parent(s) or a legal guardian is, therefore, required before they can participate in any non-exempt (and some exempt) research projects. Under special circumstances (e.g., research involving neglected/abused children) the IRB may approve a waiver of parental consent.

If the research involves only minimal risk activities (e.g., venipuncture, skin biopsy, EEG EKG, urine collection, moderate exercise, standard psychological testing), consent of only one parent or legal guardian may be obtained. If, however, the research involves greater than minimal risk activities, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, not available, or when only one parent has the legal responsibility for the care and custody of the child.

In addition to obtaining written parental/legal guardian consent, the investigator must obtain written assent of minor subjects age 7 or older, unless the subject displays intellectual/emotional development below that of the average 7 year old child. In most circumstances a child's deliberate objection should be regarded as a veto to his or her involvement in the research. However, parents and guardians, may with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the subject.

**1. Parent Consent Form**

If the subject is under the age of 7, only a parental/legal guardian consent form is required. The consent form should include all relevant elements of informed consent as outlined previously and be written in a style that indicates it is the parent or legal representative who is consenting to allowing the minor to participate in the study. The parental consent form must contain the following standard concluding consent statement in bold type or all capital letters:

**You are voluntarily making a decision whether or not to allow your child or legal ward to participate. Your signature indicates that, having read and understood the information provided above, you have decided to permit your child or legal ward to participate. You will be given a copy of this consent form to keep.**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Relationship to subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Relationship to subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness (if project involves more than minimal risk)

\_\_\_\_\_  
Signature of Investigator

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### 2. Child Assent Form

If the subject is 7 to 12 years of age, both a child assent form and a parental consent form is required. The child assent form must be brief and contain language written at the appropriate age level. Only the following elements must be present on the child assent form:

1. a statement of the purpose of the research;
2. a description of the procedures to be applied to the minor;
3. a description of the potential risks and discomforts associated with the research;
4. a description of any direct benefits to the minor;
5. a statement that the minor does not have to participate if he/she does not want to;
6. a statement that the minor is free to withdraw at any time;
7. a statement that the minor should discuss whether or not to participate with his/her parents prior to signing the assent form;
8. a statement that the parents of the minor will be asked to consent on behalf of the minor;
9. an offer to answer all questions;
10. a simplified concluding assent statement.

Only the minor and the investigator should sign the child assent form. The parent or legal guardian of the minor should be given a copy of the assent form.

### 3. Youth Assent Form

If the subject is 13 to 18 years of age, both a youth assent form and a parental consent form is required. The youth assent form must be written at the appropriate age level and contain simplified versions of the same elements present on the adult consent form. In addition, the youth assent form must contain a statement that the minor and the investigator should sign the youth assent form. The parents or legal guardian of the minor should be given a copy of the assent form.