

Approved by IRB Executive Committee: April 2, 2008
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AAHRPP Element II.7.B.

POLICY

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of research, this is accomplished by soliciting the informed consent of the prospective research participant. In the case of an adult with diminished decision-making capacity or non-autonomous child, applying the principle of respect for persons is problematic. Therefore, permission of either the parent or legally authorized representative is required. However, any individual capable of some degree of understanding (generally, a child of seven or older, or an adult with diminished decision-making capacity) should participate in research only if they assent. When assent is required by the IRB, the decision of the individual assenting should be binding.

Assent means a participant's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

In instances where the participant is a child or where the participant has diminished decision-making capacity, the IRB must find that adequate provisions are made for soliciting the assent of the participant, when in the judgment of the IRB the participant is capable of providing assent.

In determining whether participants are capable of assenting, the Investigator and the IRB shall take into account the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the participant and is available only in the context of the research, the assent of the participant is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived as stated in SOP 703.

Informed consent is an on-going process throughout the duration of a research project. When a child who was enrolled in research with parental/guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the investigator should seek and obtain legally effective informed consent, as described in SOP 701 for the now-adult participant for any ongoing interactions or interventions with the participants unless the IRB determines that the requirements for obtaining informed consent can be waived (see SOP 703). Prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult participant.

For those participants who may recover an adequate amount of decision-making capacity during the course of the study, the IRB will consider plans to obtain full informed consent from the participant as described in SOP 701.

PROCEDURES

1. Assent

- 1.1. If children capable of some degree of understanding (generally, age seven or older) or participants with diminished decision making-capability are involved in a proposed study, Investigators must provide the IRB with a plan to obtain assent.
- 1.2. The IRB determines whether some or all of the participants are capable of assent and whether assent is required. The determination is made in the Reviewer Checklist.
- 1.3. If the IRB determines that assent is a requirement, the IRB determines and documents in the Reviewer Checklist whether:
 - Adequate provisions are made for soliciting the assent of the participant.
 - Assent will be documented and the process for documentation.