

Policy Number: 33

Title: Assent/Dissent by Children or Cognitively Impaired Adults who Lack Decision-Making Capacity

Date of Last Revision: 07/28/06, 08/20/10

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assure that adequate provisions are made for soliciting the assent or dissent of children and cognitively impaired adults who lack decision-making capacity.

- I. In instances where the participant is not legally capable of giving informed consent (e.g., children) or where the participant is cognitively impaired, 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 (See IRB Policies 36 and 39)
- II. In determining whether participants are capable of assenting, 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 in accord with IRB Policy 36.
- III. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

References:

The *Belmont Report*

45 CFR 46, Subpart D

21 CFR 50, Subpart D

IRB Policy 30, "Legally Effective and Prospectively Obtained Informed Consent"

IRB Policy 32, "Waiver of Informed Consent for Human Subjects Research or Exception of Informed Consent Requirements for Emergency Research"

IRB Policy 36, "Vulnerable Populations: Children"

IRB Policy 39, "Individuals Who Are Cognitively Impaired or Mentally Disabled"

Procedure Number: 33.A

Title: Procedure for Obtaining Assent/Dissent by Children or Cognitively Impaired Adults who Lack Decision-Making Capacity

Procedure:

The purpose of this procedure is to outline the process for obtaining assent in children and cognitively impaired adults who lack the capacity for decision-making for participation in research activities.

I. Lead Researcher (LR) Responsibilities

- A. The LR will indicate the targeted study population as instructed in the "IRB Application" and provide a description in the "Protocol Narrative." When the targeted population includes children or cognitively impaired adults who lack decision-making capacity, the LR will also provide a detailed description in the protocol narrative on how assent will be obtained and documented, or request consideration of a waiver of assent.
- B. When the research participant population includes children or the cognitively impaired, the LR will complete the Vulnerable Population Appendix D for children and/or the Vulnerable Population Appendix E for cognitively impaired participants. These documents should be submitted with the "IRB Application."
- C. The LR will draft the assent documents and may utilize the assent template located on the IRB Website at <http://www.research.uci.edu/ora/forms/> under the heading "IRB Consent Forms."
- D. The LR will obtain permission from the child's parents or legal guardians in conjunction with assent requirements. Documentation of permission from the child's parents or legal guardians is provided by their signature and date on the informed consent document.
- E. Permission must also be obtained for research participants who are cognitively impaired and/or lack decision-making capacity from the individual's legally authorized representative, unless a waiver of informed consent has been granted by the IRB. Permission will be documented by the legally authorized representative's signature and date on the informed consent document.

II. IRB Committee Responsibilities

- A. The IRB Committee will review research involving children and cognitively impaired adults who lack decision-making capacity to determine whether assent is:
 - 1. Required of all participants in the proposed research; or
 - 2. Required on a case-by-case basis, when in the Investigator's opinion, the individual is able to comprehend the proposed research purpose and associated activities and procedures.
- B. The IRB Committee will also consider granting a waiver of assent in circumstances in which the targeted population does not have the ability to comprehend the proposed research purpose and/or associated procedures.
- C. The IRB Committee will consider granting a waiver of assent in circumstances in which the research holds out the 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.
- D. The IRB shall take into account the age, maturity, and psychological state of the participants involved to determine if and when assent is required and the method of documenting assent.
- E. The IRB will review the LR's plan for assessment of the research participant's ability to provide assent and determine if the plan is appropriate. The IRB will make recommendations for additional requirements, when necessary.

- F. The Reviewers will complete the "Reviewer's Supplemental Checklist for Cognitively Impaired Population" and/or the "Reviewer's Supplemental Checklist for Children."

III. **IRB Analyst or Higher Responsibilities**

- A. The Analyst will complete a pre-review of the initial study submission involving children or cognitively impaired adults who lack decision-making capacity for the inclusion of assent plan, or a request for a waiver of assent in these targeted populations.
- B. If the plan for assent is not included in the initial submission, the Analyst will request additional information from the LR.
- C. The Analyst will pre-review the assent documents assuring that each has been presented in an age appropriate language for children and in simple lay language for the cognitively impaired adults who lack decision-making capacity. The Analyst may forward recommendations for revisions to the LR prior to the meeting.
- D. The Analyst will assign the study to Reviewers who have the expertise in the area of the proposed research and the population targeted. If a member with those qualifications is not a regular Committee member, an expert consultant will be sought.

References:

The *Belmont Report*

45 CFR 46, Subpart D

IRB Policy 30, "Legally Effective and Prospectively Obtained Informed Consent"

IRB Policy 32, "Waiver of Informed Consent for Human Subjects Research or Exception of Informed Consent Requirements for Emergency Research"

IRB Policy 36, "Vulnerable Populations: Children"