Policy Number: 39
Title: Individuals Who Are Cognitively Impaired or Mentally Disabled
Date of Last Revision: 10/12/07, 10/05/10

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review, provide guidance on and approve, as applicable, research involving cognitively impaired individuals and those with mental disabilities.

I. IRB Review and Approval of Research Involving Cognitively Impaired Participants
   A. Because cognitively impaired individuals may have diminished autonomy that may limit their capacity to provide consent or their ability to withdraw, research involving cognitively impaired participants should be reviewed and approved through consideration of the UCI IRB policies and the special considerations as determined by the *Belmont Report*, Federal and State regulations, and guidance documents.
   B. The UCI IRB must review all research in which cognitively impaired individuals will be considered as participants to assure that the Investigator has provided additional safeguards to protect the rights and welfare of this vulnerable population.
   C. The IRB must consider the degree of cognitive impairment of the participant, the level of risk, and the prospect of benefit to the individual participant.

II. As a general rule, all adults, regardless of their diagnosis or condition, are presumed competent to consent unless there is evidence of a condition that would impair their reasoning or judgment.
   A. The IRB may determine that additional protections (e.g., decisional capacity assessments) are necessary to ensure that persons with fluctuating/limited decision-making capacity are capable of making a voluntary and informed decision concerning their participation in research.
   B. Research involving Minimal Risk - The IRB may require that the Investigator include a decision-making capacity assessment plan if there are reasons to believe that potential subjects' capacity may be impaired.

III. Requirements for Evaluating Decision-Making Capacity for Cognitively Impaired Participants
   A. The IRB must find that appropriate provisions are made for determining the participant's ability to provide consent or their ability to withdraw, through evidence of one or more of the following pertaining to the individual:
      1. The ability to make a choice;
      2. The ability to understand relevant information;
      3. The ability to appreciate the situation and its likely consequences; and
      4. The ability to manipulate information rationally.
   B. The determination of capacity to consent or ability to withdraw may be made through a standardized measure or consultation with another qualified professional. The IRB must approve the process for making such a determination.
   C. Because the capacity to consent or the ability to withdraw may fluctuate, the IRB must evaluate the process for continued verification of understanding and willingness to participate.

D. For participants who lack decision-making capacity, the IRB may grant approval to obtain the permission of the individual's surrogate decision maker and the assent of the participant (See IRB Procedure 30.C).
   1. Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subject.
   2. In research situations where there is the potential for direct benefit to the participant, the IRB may waive the requirement to obtain assent. However, permission from the surrogate decision maker must be obtained.
   3. Even where the IRB determines that the individuals are capable of consenting or withdrawing from the research, the IRB may still waive the consent requirements under the circumstances described in the UCI IRB informed consent policy (See IRB Policy 32)

E. The IRB must also review and approve the appropriate consent documents with the required elements of consent written in a language understandable to the participant.

IV. Appropriate Provisions for Legally Authorized Representative Consent

When it is determined by the Investigator that the participant lacks decision-making capacity; the IRB must find that appropriate provisions are made for soliciting the permission of a surrogate decision maker unless the criteria are met to approve a waiver of informed consent (See IRB Policy 32)

V. Institutionalized Participants

A. Surrogate consent to participate in research under California Health & Safety Code Section 24178 is not permitted for persons on an inpatient psychiatric ward, inpatients of a mental health facility, or persons on psychiatric hold.

B. The IRB must consider the rationale and justification for involvement of institutionalized participants, including an explanation as to why non-institutionalized individuals could not be used.

C. Regardless of financial support or funding, the UCI IRB must assure that all performance sites "engaged" in research have approval from the IRB of Record for the proposed research to be conducted at the site.

D. When performance sites are "not engaged" in research and have an established IRB, the Investigator must obtain approval to conduct the research at the "not engaged" site from the site's IRB or provide documentation that the site's IRB has determined that approval is not necessary for UC Irvine to conduct the proposed research at the site.

E. When performance sites are "not engaged" in research and the "not engaged" site does not have an established IRB, a letter of cooperation/permission must be obtained demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.

VI. Composition of IRB when Cognitively Impaired Participants are Involved in Research

A. When reviewing research involving cognitively impaired participants, the IRB Committee will include in its composition one or more individuals who are knowledgeable about and experienced in working with cognitively impaired individuals.
   1. When reviewing research funded by the National Institute on Disability and Rehabilitation Research, should the research purposefully include individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

B. When the study requires review by the full IRB Committee, it must meet the special composition requirements when conducting reviews for initial review, continuing review, and significant protocol modifications/amendments.

References:

The Belmont Report
Am J Psychiatry 155:11, November 1998, “Guidelines for Assessing the Decision-Making Capacities of Potential Research Subjects with Cognitive Impairment”
The Office of Human Subjects Research (OHSR), National Institutes of Health, Information Sheet #7, “Research Involving Cognitively Impaired Subjects: A Review of Some Ethical Considerations”
California Health & Safety Code Section 24178
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 for Emergency Research”
34 CFR 356.3

Procedure Number: 39.A

Title: Procedure for Review of Research Involving Individuals Who Are Cognitively Impaired or Mentally Disabled

Procedure:

This procedure provides guidance on the special ethical and regulatory considerations of cognitively impaired individuals involved in human subjects research under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

I. Lead Researcher (LR) Responsibilities

A. The LR will submit the IRB "Vulnerable Populations - Cognitively Impaired/Medically Incapacitated Subjects and Use of Surrogate Consent" (Appendix E) with any new study submission in which cognitively impaired participants will be a target population for research activities.

B. The research plan should address the following considerations:

1. A rationale as to why is it necessary to include this population;
2. A description of potential benefits to this population;
3. A justification for the use of institutionalized individuals, if applicable;
4. A description of the research as it pertains to the institutionalization, if applicable;
5. A description of the procedure for determining capacity for decision-making of the individuals;
6. A description as to how individuals will be protected in the event they lose their capacity to consent and their capacity to withdraw;
7. A description of the methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered; and
8. A description as to how permission will be obtained and documented from the legally authorized representative, if applicable;

C. A Lead Researcher should not solicit consent of a participant who lacks decision-making capacity without intending to take his/her wishes seriously. In situations where the potential benefits of the study are such that the physicians and surrogate decision-maker would enroll the participant regardless, and the participant's capacity is so diminished that he/she could not understand the ramifications of not participating, the participant should simply be told what is planned and should not be deceived.

1. A request of wavier for consent should be submitted to the IRB for determination (See IRB Procedure 32.A).
2. Should a situation exist in which the target population lacks decision-making capacity either through trauma, life-threatening condition, or coma, the LR may submit a request for surrogate consent (See IRB Policy 30).

D. The LR must present an informed consent document to the IRB for review containing the appropriate amount of information for the participant to make an informed decision. If, in the opinion of the Investigator, a complete informed consent document is not appropriate, a waiver or alteration of informed consent (Appendix O) should be requested including a rationale for the alteration.

E. Once approved, the LR may proceed with consent of the participant and/or surrogate decision-maker as outlined in IRB Policy 30, unless a waiver has been granted.

F. If the research will involve institutionalized participants and depending on whether the performance site is "engaged in research", a letter of IRB approval or a letter of cooperation from the institutional official from that site must be submitted to the IRB for review and approval.

II. IRB Committee Responsibilities

A. The IRB Committee must review the proposed research taking into consideration all applicable UCI policies and procedures and California law (See IRB Policy 30), as well as the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the participant. In addition, the IRB must be sure that additional safeguards are in place to protect the rights and welfare of these participants.

B. When determining whether the participants are capable of providing consent, the IRB shall take into account the decision-making capacity of the study population. This determination may apply to all participants to be involved in the study, some participants, or on a case-by-case basis, as deemed necessary by the IRB.

C. When the IRB evaluates the LR's proposed plan for assessing the decision-making capacity of study population, the IRB considers such factors as:
   1. The criteria that will be used for determining the participants' capacity for providing informed consent;
   2. The appropriateness and adequacy of method(s) by which the prospective participants' decisional capacity will be evaluated (e.g., whether selected tools for assessing competency to consent are acceptable and appropriate);
   3. The qualifications of the proposed individual(s) that will assess the participants' decision-making capacity.

D. The IRB may require additional protections to ensure that informed consent from the subject is/has been obtained whenever possible. Examples include, but are not limited to, the following as appropriate:
   1. Periodic re-consenting;
   2. Use of third party consent monitors during the recruitment and consent process;
   3. Required waiting periods to allow more time for the participant to consider the information that has been presented;
   4. Obtaining second opinions, using independent consent observers and/or involving a trusted family member or friend in the disclosure and decision-making process; and/or
   5. For subjects with limited decision capacity, requiring the subject's assent.

E. The methods in which the full IRB Committee approves a new IRB Application will be followed. In addition to determining whether the study meets criteria 45 CFR 46.111 for approval, the Primary and Secondary Reviewers must also complete the "Supplemental Reviewer's Checklist for Cognitively Impaired Population and Surrogate Consent" to assure that adequate provisions and documentation of such provisions have been made for this population.

F. The Committee may not review or make a determination regarding studies involving the cognitively impaired, as a target population, unless it has sufficient expertise in the ethical, clinical, and psychosocial issues impacting this population. Therefore, a Committee member who is knowledgeable about and experienced in working with these subjects must be in attendance at the convened meeting or an expert consultant who has this knowledge must be consulted by the IRB. When the IRB Committee renders its determination it will include:
   1. Requirements for determining the decision-making capacity of the target population or on a case-by-case basis, or a rationale why this requirement will be waived; and
   2. Appropriate methods for assuring the amount of information contained in the consent document are appropriate for the target population and the surrogate decision-maker, when necessary.

G. When institutionalized individuals are involved in research, the IRB must verify that the institution has granted approval for the research to take place at that site. Depending on

III. IRB Analyst or Higher Responsibilities

A. The Analyst will verify that the "Vulnerable Populations - Cognitively Impaired/Medically Incapacitated Subjects and Use of Surrogate Consent" (Appendix E) is completed as part of the initial study documents.

B. The Analyst will conduct a pre-review and take into consideration the capacity of the participants in the proposed research when pre-reviewing the IRB Application, protocol narrative and informed consent documents.

C. E-mails recommending pre-review changes to the protocol or informed consent documents are to be sent to the LR by the Analyst.

D. Once the pre-review revisions are received from the LR, the Administrator will forward the revised documents to the assigned Reviewers.

References:

IRB Policy 30, "Legally Effective and Prospectively Obtained Informed Consent"
IRB Procedure 32.A, "Procedure for Waiver or Exception of Informed Consent for Human Subjects Research"