RESEARCH INVOLVING INDIVIDUALS WITH DECISIONAL IMPAIRMENT
(NON-VA RESEARCH)

Definitions

**Decisional Impairment:** This term is used when an individual has a diminished capacity for understanding information and for making a reasoned decision due to a disorder that affects cognitive or emotional functions. Other individuals may be considered to have a decisional impairment because they have a degenerative disease affecting decision-making capacity or are comatose or otherwise incapacitated. The terms “decisional impairment” and “diminished decisional capacity” may be used interchangeably in this document.

**Legally Authorized Representative (LAR):** For the purposes of research, an LAR is “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research” [45 CFR 46.102, 21 CFR 50.3(1)].

Under the general requirements for informed consent as defined in the federal regulations, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s LAR. In the event that the research involves adults unable to provide consent, a legal authorized representative (LAR) may be used (i.e. proxy or surrogate consent).

Utah provides a list of individuals who are authorized to consent to medical treatment for another when the patient is unable to consent on his or her own behalf. The statute provides that the consent must not be otherwise prohibited by law. The statute provides that the following individuals may consent on behalf of another. These individuals will be considered to meet the DHHS and FDA definition of a legally authorized representative for research purposes:

- Any married person, for a spouse
- Any person 18 years of age or older for his or her parent who is unable by reason of age, physical or mental condition, to provide such consent

Utah recognizes special power of attorney documents and medical directives in which individuals can provide advance directives of medical care in the event the individual is not able to make his or her wishes known. Through power of attorney documents, an individual can also name another individual who can consent on his or her behalf. These documents will be notarized and will outline the authority of the second person to make decisions for the patient. In addition, courts can appoint guardians who can make medical and other decisions for individuals who are incapacitated. The guardian will receive court documents that outline their authority to make decisions for the patient. For information on interpreting these documents, contact the Office of General Counsel. Such individuals documented as having power of attorney or appointed guardians will be considered to meet the DHHS and FDA definitions of a legally authorized representative for research purposes.

The University of Utah IRB will accept consent from an LAR given that the researcher has established that the consenting individual has legal authority to do so (provided the IRB determined there is adequate justification for the inclusion of an LAR in the consent process).

**Description**

*Please note that there are differences in requirements for the inclusion of incompetent people or people with impaired decision making capacity for VA research. Please see the separate document, Investigator Guidance Series: VA Research Involving Individuals with...*
**Decisional Impairment on the IRB website.**

Cognitive impairment and mental disability is not always associated with the lack of capacity to provide informed consent to participate in research. Exclusion of individuals with cognitive impairment for that reason only is discriminatory and does not allow for the equitable selection of subjects.

However, investigators must provide a compelling reason to include cognitively impaired individuals as participants, as these individuals should not be included in research simply because they are readily available. The research should have an appropriate risk:benefit ratio, entailing no significant risks or providing a greater probability of direct benefit if significant risks exist.

The IRB may approve non-VA research involving cognitively impaired individuals only if the research falls into one of the following three categories:

1. Research involving no greater than minimal risk.
2. Research involving interventions or procedures that present greater than minimal risk but offers the prospect of direct benefit or may contribute to the well-being of the individual.
3. Research involving interventions or procedures that present a minor increase over minimal risk and no prospect of direct benefit to individuals, but likely to yield generalizable knowledge about the individual's disorder or condition.

**Screening for Cognitive Impairment & Evaluating Capacity to Consent to Research**

In the context of human subject research, there is the concern that decisional impairment may compromise an individual’s capacity to understand the information presented in the consent process and affect his/her ability to make a reasoned decision about participation in a research study.

The level and permanency of the decisional impairment of the potential research participant is a critical factor when determining the capacity of the individual to consent to participate in research. The impairment may be partial/minor or full/severe, and the impairment may be permanent or transitory.

An investigator’s assessment of a person’s abilities to understand information about a study and to reason and make a choice on the basis of that information is essential evidence for the judgment of whether the person is competent to provide informed consent. Protocols for studies that enroll cognitively impaired subjects should describe a procedure to assess these abilities, and the process for making that determination should be outlined in the application to the IRB.

Psychiatric consultation may be helpful in complex cases or when mental illness is present and the IRB may recommend or require such consultation prior to enrollment. Given the possibility of fluctuations in the patient’s mental state (i.e. level of capacity) and the gravity of depriving a patient of their right to make decisions for themselves, when the possibility exists that the decision be made that a patient is not competent, clear procedures for making the determination should be outlined in the application to the IRB.

**Considerations for Obtaining Informed Consent**

When participants cannot give full informed consent for themselves, the investigator may use different models to obtain consent. Depending on the cognitive capacity of the participant, the investigator may obtain verbal or documented assent from the participant with full informed consent obtained from the participant’s legally authorized representative (LAR). However, there may be times when a participant’s cognitive capacity does not allow for obtaining assent, in which case obtaining only full informed consent form the participant’s LAR is appropriate.

An LAR must be provided with a description of the research (e.g. the consent document) and be

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
informed of his/her role and obligation to protect the rights and welfare of the participant. An LAR must be informed that the obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant’s wishes cannot be determined, what is in the participant’s best interests.

Although some individuals may not have the capacity to provide full informed consent, these individuals may resist participating in a research protocol approved by their LARs. Under no circumstances may participants be forced or coerced to participate.

**Fluctuating Capacity to Provide Informed Consent**

Both investigators and IRB members must be aware that the decision making capacity of some individuals may fluctuate. For participants with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consent or re-assent process, with or without an LAR, may be necessary.

For participants where there is a predicted loss of cognitive capacity (e.g. before the administration of anesthesia), advance informed consent is an option. When advance informed consent is obtained, investigators should also ask each participant to designate a person who will serve as his or her proxy during the course of the research.

If there is predicted regaining of cognitive capacity (e.g. after surgery or coma), it may be necessary to seek full informed consent from the participant at that time. This must be considered even if an LAR was used to obtain full informed consent before cognitive capacity was restored.

**Points to Address**

<table>
<thead>
<tr>
<th>New Study Application:</th>
<th>Vulnerable Populations page, question 1: Please provide justification that there is a compelling reason to include cognitively impaired individuals or persons with impaired decision making capacity as participants.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risks and Benefits page, questions 6.1 and 6.2: Please provide a description of the risks and benefits to cognitively impaired individuals or persons with impaired decision making capacity. If the research poses greater than minimal risk to the participants, please provide justification why the probability of benefit is greater than the probability of harm.</td>
</tr>
<tr>
<td>Consent Process page, Section 6:</td>
<td>Please select “Yes” to indicate if you intend to use a Legally Authorized Representative (LAR) as a part of your consent process. Please explain when the use of an LAR may arise in this study population and what the frequency of an LAR might be during the enrollment period.</td>
</tr>
<tr>
<td>Additional Consent Considerations page, question 2:</td>
<td>Please discuss whether obtaining assent from the adult with impaired decision making capacity and informed consent from an LAR is appropriate for the study. Please also discuss whether periodic re-consenting or re-assenting is appropriate to ensure a participant’s continued involvement is voluntary and to accommodate fluctuating decision making capacity.</td>
</tr>
<tr>
<td>Consent Document:</td>
<td>LAR Signature Block: Please add the LAR Signature Block to the end of your consent document. See the IRB Consent Template for language.</td>
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</tbody>
</table>

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References & Links

University of Utah IRB SOP 501
http://www.research.utah.edu/irb/guidelines/sop.html

IRB Consent Template
http://www.research.utah.edu/irb/forms/hipaa/word/biomed_consent-32.doc

Investigator Guidance Series: VA Research Involving Individuals with Decisional Impairment
http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

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