



RESEARCH INVOLVING INDIVIDUALS WITH DECISIONAL IMPAIRMENT

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 and is an acceptable legally authorized representative in accordance with VA policy:

- 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 and is an acceptable legally authorized representative in accordance with VA policy.

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

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.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



However, investigators must provide a compelling reason to include individuals with impaired decision-making capacity as participants, as these individuals should not be included in research simply because they are readily available. The IRB may approve research involving individuals with impaired decision-making capacity only as described below:

1. The proposed research involves interventions or procedures presenting:
 - No greater than minimal risk to the subject as determined by the IRB; or
 - Greater than minimal risk but offers the prospect of direct benefits or may contribute to the well-being of the individual;
 - A minor increase over minimal risk and no prospect of direct benefit to individuals, but is likely to yield generalizable knowledge about the individual's disorder or condition that is of vital importance for the understanding or amelioration of the individual's disorder or condition.
2. The intent of the research is to study:
 - The disorder leading to the individual's lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke), but only if the study cannot be performed with only persons who have decision-making capability; or
 - A disorder which is not directly related to the individual's lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study.

Screening for Decisional 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 individuals with decisional impairment should describe a procedure to assess these abilities, and the process for making that determination should be outlined in the application to the IRB.

An individual is presumed to have decision-making capacity **unless** one or more of the following apply:

- It has been documented by a qualified practitioner in the individual's medical record in a signed and dated progress note that the individual lacks capacity to make the decision to participate in the proposed study. *NOTE: The qualified practitioner may be a member of the research team.*
- The individual has been ruled incompetent by a court of law.

If neither of the above has occurred and there is any question as to whether or not a potential adult subject has decision-making capacity, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the informed consent process.

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.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



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 decision making 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.

Individuals, who because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity must be evaluated by a qualified practitioner (who may be a member of the research team), to determine the individual's ability to provide informed consent. This evaluation must be performed as described in the IRB-approved protocol. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a LAR must provide informed consent. If the subject regains decision-making capacity, the investigator or designee must repeat the informed consent process with the subject, and obtain the subject's permission to continue with the study.

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 from the participant's LAR is appropriate.

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

Investigators must provide information (i.e., informed consent document and HIPAA authorization) to the subjects' LARs that would ordinarily be required to the subjects themselves if they had decision-making capacity.

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. The study must include appropriate procedures for respecting dissent.

Points to Address

New Study Application:

Participants page, question 3: Please select "Individuals with Cognitive or Decisional Impairment". The subsequent page will request justification that there is a compelling reason to include persons with impaired decision-making capacity as participants.

Risks and Benefits page: Please provide a description of the risks and benefits to 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.

Consent Process page, question 6: Please select "Yes" to indicate if you intend to use a Legally Authorized Representative (LAR) as a part of your consent process. Please

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



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.

Additional Consent Considerations page: 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.

Consent Document:

LAR Signature Block: Please add the LAR Signature Block to the end of your consent document. See the IRB Consent Template for language.

References & Links

*University of Utah IRB SOP
501*

<http://irb.utah.edu/guidelines/irb-sops.php>

IRB Consent Template

<http://irb.utah.edu/forms/health-sciences.php>

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.