

Investigator Guidance Series

University of Utah Institutional Review Board

VA 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

Please note that there are differences in requirements for the inclusion of cognitively impaired or mentally disabled individuals for VA hospitals and non-VA hospitals. If you will be conducting non-VA research, refer to the separate document, Investigator Guidance

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

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Series: Research Involving Individuals with Decisional Impairment on the IRB website.

VA Requirements for Individuals with Impaired Decision Making Capacity

In order for incompetent persons or persons with impaired decision making capacity to be included in research conducted at the VA, the IRB must document that the following requirements have been met:

1. The inclusion of incompetent persons or persons with impaired decision making capacity must be necessary to answering the research question. If the research can be conducted on competent persons, incompetent persons or persons with impaired decision making capacity may not be included. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or person with impaired decision making capacity as participants, as these individuals should not be included in research simply because they are readily available.
2. The proposed research must not entail any significant risks, tangible or intangible. If the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision making capacity are not to be subjects of research that imposes risk of injury, unless the research is intended to benefit the subject and the probability of benefit is greater than the probability of harm.
3. Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. The legally authorized representative (LAR) must be given descriptions of both proposed research studies and the obligations of the LAR. The LAR must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

Requirements for Obtaining Informed Consent

In the case of participants who 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.

Informed consent given by an LAR for VA research may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision making capacity as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements or as established by a legal determination:

- The practitioner, in consultation with the chief of service (COS), may determine after appropriate medical evaluation that the prospective research participant lacks decision making capacity and is unlikely to regain it within a reasonable period of time.
- Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision making capacity is based on a diagnosis of mental illness.
- Any required disclosures (e.g. informed consent requirements) to the subject by the investigator must be made to the research subject's surrogate.
- If feasible, the practitioner must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a

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subject be forced or coerced to participate in a research study.

Fluctuating Capacity to Provide Informed Consent

Both investigators and IRB members must be aware that for some subjects, their decision making capacity 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 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

New Study Application:

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.

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.

Consent Process page, Section 6: 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.

Additional Consent Considerations page, question 2: 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.

VA 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://www.research.utah.edu/irb/guidelines/sop.html>

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<i>VHA Handbook 1200.5</i>	http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=1727
<i>Salt Lake City VA Investigator Handbook</i>	http://www.research.utah.edu/irb/guidelines/va_policies.html
<i>IRB VA Consent Template</i>	http://www.research.utah.edu/irb/forms/hipaa/index.html
<i>Investigator Guidance Series: Research Involving Individuals with Decisional Impairment (Non-VA Research)</i>	http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

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