



RESEARCH INVOLVING INDIVIDUALS WITH DECISIONAL IMPAIRMENT

Description

The University of Utah IRB must determine that the selection of subjects is equitable in order to approve research. In particular, the IRB must be aware of special issues surrounding research that involves individuals with impaired decision-making capacity.¹ This guidance outlines the information that the investigator must provide to the IRB in their consideration of the inclusion of individuals with impaired decision-making capacity.

Definitions

- A. **Assent** means a participant’s affirmative agreement to participate in research. In this guidance, *assent* refers to the affirmative agreement of individuals with diminished decision-making capability to participate in research. The absence of an objection, without affirmative agreement, should not be interpreted as assent.
- A. **Decisional Impairment** is a term 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 have a serious/life-threatening diseases and conditions which leave them comatose or otherwise incapacitated. The terms “decisional impairment” and “diminished decisional capacity” may be used interchangeably in this document.
- B. For the purposes of research, a **Legally Authorized Representative (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. If the research involves adults unable to provide consent, a legal authorized representative (LAR) may be used for surrogate consent provided the IRB determines there is adequate justification for inclusion of an LAR in the consent process.

Understanding the University of Utah IRB Approval Criteria

Cognitive impairment and mental disability are not always correlated 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 individuals with impaired decision-making capacity as participants, as these individuals should not be included in research simply because they are readily available.

The University of Utah IRB established guidelines for research involving participants with impaired decision-making capacity or a mental disability². While not all cognitively impaired or mentally disabled persons will have impaired decision-making capacity, the University of Utah guidelines are aimed at providing additional safeguards for the participants.

The IRB may approve research involving individuals with impaired decision-making capacity only as described below:

¹ 45 CFR 46.111(a)(3)

² 21 CFR 56.111(b)

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



1. The proposed research involves interventions or procedures presenting (at least one must apply):
 - No greater than minimal risk to the subject as determined by the IRB.
 - 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 (one must apply):
 - The disorder leading to the individual's lack of decision-making capacity, whether 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.
 - 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. *For Department of Defense-conducted or supported research, the intention of the investigator must be for the research to be beneficial to the subject.*

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 based on 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.

- The research team should indicate the inclusion of "Individuals with Cognitive or Decisional Impairment" or "Mentally Disabled" is indicated on the Participants (3) page in the ERICA application. Then, the procedure used to assess participants' ability to provide consent should be described on the "Additional Consent Considerations" page.

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 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 decision-making capacity) and the gravity of depriving a patient of their right to make decisions for themselves, when the

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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.

Fluctuating Capacity to Provide Informed Consent

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 surrogate 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

After an assessment is made and it appears that there is impaired decision-making capacity, the investigator will either need to exclude the prospective participant from the study or seek surrogate consent from the participants' LAR. Please see the Investigator Guidance Series: Surrogate Consent by a Legally Authorized Representative for more guidance regarding the use of surrogate consent.

- The investigator should clearly outline the plan to either exclude the prospective participant or obtain surrogate consent (with assent, as appropriate) in the research application on the [Consent Process page](#).

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 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.

Assent for Individuals with Diminished Decision-Making Capacity

Although there are no federal regulations governing assent for adults with diminished decision-making capacity, it is the policy of the University of Utah IRB to ensure 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.

The investigator should consider an assent process (accompanied by consent from a legal authorized representative) for persons with diminished decision-making capacity. Additional considerations for adults with diminished decision-making capacity such as:

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- Should a re-assenting or re-consenting process take place throughout the study to ensure voluntary participation?
- For those participants who may recover an adequate amount of decision-making capacity, are there plans to obtain full informed consent from the participant?

Points to Address

New Study Application:

1. **Participants page, question 3:** Please select “Individuals with Cognitive or Decisional Impairment” or “Mentally Disabled”, as applicable.
2. **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.
3. **Consent Process page, question 6:** Please select “Yes” 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 during this study and with this study population and what the frequency of an LAR might be during the enrollment period.
 - Provide the protocol-specific, descending order of priority list of individuals who may be sought as an LAR.
 - Describe the procedures for screening and determining whether an LAR has authority to consent on behalf of the participant.
 - The investigator should also confirm that they will inform the LAR of their responsibilities.
4. **Additional Consent Considerations page, question 1:** Describe the nature of the cognitive/decisional impairment or mental disability that affects decision-making ability. Please provide justification that there is a compelling reason to include persons with impaired decision-making capacity or a mental disability in the research.
5. **Additional Consent Considerations page, question 2:** State whether obtaining assent from the adult with impaired decision-making is appropriate for the study.
6. **Additional Consent Considerations, question 3:** State 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: If an LAR will be used to consent individuals with diminished decision-making capacity, please add the LAR Signature Block to the end of your consent document. See Signature Block Samples on the IRB website for the LAR signature block (link below).

References & Links

*Investigator Guidance Series:
Surrogate Consent by a
Legally Authorized
Representative*

<https://irb.utah.edu/guidelines/investigator.php>

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*Signature Block Samples
and LAR Signature Page*

<https://irb.utah.edu/forms/index.php>

*University of Utah IRB SOP
501: Vulnerable Populations*

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

*How to Refer to People with
Disabilities*

<https://www.ncbi.nlm.nih.gov/books/NBK64884/>

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