

ETHICAL CONSIDERATIONS FOR SURROGATE CONSENT

Description

Federal regulations permit investigators to obtain surrogate consent from a legally authorized representative. Utah law¹ and University of Utah Institutional policy define the categories of individuals who are permitted to provide surrogate consent for research. The University of Utah Institutional Review Board (IRB) must approve the use of surrogate consent.

Definitions

- A. Assent:** Assent is a term used to express willingness to participate in research who are too young to give informed consent or do not have the decision-making capacity to give informed consent.
- B. Legally Authorized Representative (LAR):** For the purposes of research, the Food and Drug Administration (FDA) defines an LAR as 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.² The federal Department of Health and Human Services (DHHS) further states that if there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.³

The VA defines a legally authorized representative (LAR) as 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. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

- C. Surrogate Consent:** Surrogate consent is when a legally authorized representative provides consent on behalf of a research subject to be included in research. The terms proxy consent and parental permission are also considered to be surrogate consent.

IRB Considerations for Research Involving Individuals with Impaired Decision-Making Capacity

To allow for research involving individuals with impaired decision-making capacity, the board must consider both the risk of the research and the intent of the research. When the participant recruitment plan includes individuals who have a condition of a type and severity likely to lead to impairment to functional abilities to the extent that it might affect capacity to consent, the IRB should consider whether surrogate consent is acceptable. These include, but are not limited to:

- Acute medical conditions
- Psychiatric disorders
- Neurologic disorders
- Developmental disorders
- Behavioral disorders

If researchers or IRB members are uncertain as to whether a given condition might be associated with diminished functional abilities, they should consult a health professional who regularly interacts with individuals with the relevant condition.

¹ Advance Health Care Directive Act [Utah Code 75-2a-101 et. seq.]

² 21 CFR 50.3(l)

³ 45 CFR 46.102(i)

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

This policy was developed by the University of Utah IRB to ensure adequate protection for individuals with impaired decision-making capability. The board member checklist includes the following considerations for research involving individuals with impaired decision-making capacity and is provided here for your reference.

Risk of Research

The research presents (at least one must apply):

- Greater than minimal risk but offers the prospect of direct benefit(s) or may contribute to the well-being of the individual.
- A minor increase over minimal risk and no prospect of direct benefit to the participants 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.
- No greater than minimal risk to the subject as determined by the IRB.

Intent of Research

The intent of the research is to the study (one must apply):

- The disorder leading to the individual's decision-making capacity, if the study cannot be performed with only persons who retain decision-making capability.
- A disorder 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.

Consent and Assent Considerations

Would an assent process be appropriate along with proxy consent from an LAR?

- Should a re-assenting or re-consenting process take place throughout the study to ensure voluntary participation?

Who May Provide Surrogate Consent?

Investigators are asked to carefully consider the research intent, the risk involved in the research procedures, and the population of the research participants. The investigator should present a list to the IRB of individuals who may be able to provide surrogate consent. The board should review the list of individuals and may require changes or adjustments depending upon the research study.

- Investigators must outline the protocol-specific descending order of priority of individuals who may be sought as a legally authorized representative in the ERICA application (Consent Process page, question 6).

In descending order of priority, the following individuals, if willing and able, may be considered to provide surrogate consent for a research participant as outlined in **Chart 1** below.

1. A person designated by the research participant, while retaining the decisional capacity to do so, to make decisions for her/him/them regarding participation in research or health care decisions.
 - *Example: The [Utah Advance Health Care Directive](#) designates a health care agent. The AHCD states whether a surrogate decision-maker may consent to participation in medical research or clinical trials. The health care agent may act as the LAR.*
 - *Example: An individual has been granted legal guardianship by a court. The guardian may act as the LAR.*
2. Spouse (unless legally separated or a court finds the spouse has acted in a manner that should preclude the spouse from having a priority position as a surrogate decision maker).
3. An adult child (18 years of age or older) for a parent
4. A parent for an adult child
5. An adult sibling
6. A grandparent for an adult grandchild
7. An adult grandchild (18 years of age or older) for a grandparent

Continued on page 3

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CHART 1

The proposed research involves interventions or procedures presenting:	Intent of 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, but only if the study cannot be performed with only persons who have decision-making capability.*	Intent of research is to study 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.**
No greater than minimal risk	Individuals 1-4 generally acceptable; Individuals 5-7 may be considered with compelling rationale	Individuals 1-4 generally acceptable; Individuals 5-7 may be considered with compelling rationale
Greater than minimal risk but offers the prospect of direct benefits or may contribute to the well-being of the individual	Individuals 1-3 generally acceptable; Individuals 4-5 may be considered with compelling rationale	Individuals 1-3 generally acceptable; Individuals 4-5 may be considered with compelling rationale
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	Individuals 1-3 may be considered	Individuals 1-3 may be considered

* For example, an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke.

** For Department of Defense-conducted or supported research, the intention of the investigator must be for the research to be beneficial to the subject.

Consent and Assent for Individuals with Impaired Decision-Making Capacity

The investigator should provide information in the IRB application to help the board make the required determinations. The board may use the information in the application to determine whether allowing the use of an LAR is acceptable, and which category of individuals may be allowed to provide surrogate consent. Board members can find important information in the application, located on the Consent Process page and the Additional Consent Considerations page.

On the Consent Process Page (question 6):

- Has the investigator described when the use of a Legally Authorized Representative (LAR) may arise during the study or with the study population, and what the frequency of an LAR might be during the enrollment period?
- Has the investigator provided a protocol-specific, descending order of priority list of individuals who may be sought as an LAR?
- Has the investigator provided a description of the procedures for screening and determining whether an LAR has authority to consent on behalf of the participant?
- Has the investigator confirmed that the participant's LAR will be well-informed regarding their roles and obligations to protect the research participant?

On the Additional Consent Considerations Page:

- **(Question 1)** Has the investigator described the nature of the cognitive/decisional impairment or mental disability that affects decision-making ability?
- **(Question 1)** Has the investigator provided a compelling reason to include persons with impaired decision-making capacity or a mental disability in the research?
- **(Question 2):** Has the investigator stated whether obtaining assent from the individual with impaired decision-making capacity is appropriate for the study?

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- **(Question 3):** Has the investigator stated whether periodic re-consenting or re-assenting is appropriate for those participants who may recover an adequate amount of decision-making capacity?

References & Links

*Investigator Guidance Series:
Research Involving Individuals
with Decisional Impairment*

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

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

*Utah Advance Health Care
Directives*

<https://ucoa.utah.edu/coreissues/directives/>

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