

SURROGATE CONSENT BY A LEGALLY AUTHORIZED REPRESENTATIVE

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. This guidance outlines when surrogate consent by a legally authorized representative (LAR) is allowable.

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.

When is Surrogate Consent Allowed by the University of Utah IRB?

Surrogate consent is allowed in the research context in specific situations when the University of Utah IRB has approved its use. The IRB may consider the use of surrogate consent for research studies that involve participants with cognitive impairment, lack of decision-making capacity, or serious or life-threatening diseases and conditions. 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 [Investigator Guidance Series: Research Involving Individuals with Decisional Impairment](#) outlines the information that the investigator must provide to the IRB in their consideration of the inclusion of individuals with impaired decision-making capacity. **If the IRB has not yet approved the use of surrogate consent, an amendment should be submitted to the IRB before a researcher obtains surrogate consent from an LAR.**

IRB Approval to Obtain Surrogate Consent from an LAR

The IRB will consider an investigator's intent to obtain surrogate consent. First, it is important for the investigator to understand the University of Utah IRB's approval criteria for research involving individuals with impaired decision-making

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.



capacity. Investigators should review [Investigator Guidance Series: Research Involving Individuals with Decisional Impairment](#) to adequately prepare their application for IRB review. The investigator must provide the following information for the board to determine whether the use of surrogate consent is allowed.

1. **Justification for Surrogate Consent:** A protocol-specific plan should be outlined as to why the IRB should approve the research involving individuals with impaired decision-making capacity.
 - ☑ On the Participants (3) page of the ERICA application, make sure to select the vulnerable participant group which will be included (individuals with cognitive or decisional impairment, or mentally disabled⁴). The application will populate an additional page which allows the investigator to describe the participant group, and how it affects decision-making ability. Additionally, the investigator will be asked to provide information regarding an assent process and whether a re-consent procedure will be considered for that participant group.
2. **Consent Process:** For each participant who is determined incapable of providing consent or appointing an LAR, investigators should outline the plan to ensure that consent is sought from an LAR, consistent with applicable law. Some participants deemed incapable of providing consent might be capable of appointing a LAR and should be encouraged to appoint one if they have not done so already. If feasible, such a process allowing the research participant to appoint an LAR for the research should be outlined.
 - ☑ On the Consent Process page (question 6) of the ERICA application, make sure to indicate that a legally authorized representative (LAR) will be used. 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.
 - ☑ The consent document should have a signature block that includes documentation of consent by an LAR.

Determining Who May Provide Surrogate Consent

Investigators are responsible for determining and documenting that an individual has the legal authority to provide surrogate consent as a legally authorized representative. A person's eligibility to serve as a legally authorized representative depends on state law and institutional policies.

- ☑ 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).

The investigator must 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 IRB will review the list of individuals and may require changes or adjustments depending upon the research study.

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.

⁴ The term "mentally disabled" is a term currently used by the FDA in 21 CFR 56. The IRB acknowledges that an individual that may be considered mentally disabled may still have the ability to understand the choices presented and to make a decision of whether or not to participate in a study.

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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

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.

Documenting Surrogate Consent by an LAR

If the IRB has approved the use of surrogate consent by an LAR, an LAR signature block should be included in the approved IRB consent document. Documentation of the LAR's relationship to the participant is made using the declaration of relationship in the LAR signature block. It is the responsibility of the person obtaining consent to ensure that this portion of the signature block is completed. See Appendix A to view the LAR signature block. For a Word version that may be copied and pasted, please see the [Forms and Templates page](#) on the IRB website.

Research teams should seek to establish and verify the relationship between the study participant and the surrogate decision-maker prior to obtaining consent. Researchers may consult with the Office of General Counsel and/or Risk Management if there are questions regarding the identification of the surrogate decision-maker. The IRB does not require copies of documents that were used to verify the relationship between the study participant and the surrogate decision-maker to be retained in research files, however, a research team may consider this as a standard practice when using an LAR.

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

Points to Address

New Study Application:

1. **Participants (3) page:** Please select “Individuals with Cognitive or Decisional Impairment” or “Mentally Disabled”, as applicable.
2. **Consent Process page, question 6:** Please select “yes” to if you intend to use a Legally Authorized Representative (LAR) as part of your consent process.
 - Please explain when the use of an LAR may arise during this study or with the 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.
3. **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.
4. **Additional Consent Considerations page, question 2:** State whether obtaining assent from the adult with impaired decision-making capacity is appropriate for the study.
5. **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:
Research Involving Individuals
with Decisional Impairment* <https://irb.utah.edu/guidelines/investigator.php>

*Signature Block Samples and
LAR Signature Page* <https://irb.utah.edu/forms/index.php>

*Utah Advance Health Care
Directives* <https://ucoa.utah.edu/coreissues/directives/>

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Appendix A: LAR Signature Block

The following sample signature block for a Legally Authorized Representatives (LAR) may be included at the end of consent the documents if it has been explained in the new study application and approved by the IRB.

Alternatively, investigators may use a separate LAR Signature Page that may be used to document the legally authorized representative's signature in conjunction with an approved consent document. The [Forms and Templates](#) page of the IRB website has both . This language is available on the Signature Block Samples template on the

If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:

I confirm that I have read the consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

Participant's Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my 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. I will be given a signed copy of the consent and authorization form to keep.

Name of Authorized Personal Representative

Signature of Authorized Personal Representative

Date

Check the category that best describes the surrogate decision maker's relationship to the study participant: ***Only use categories of individuals that have been approved by the IRB for this research study.***

- Individual authorized with legal authority to provide consent on behalf of the participant (e.g., an individual named in an Advance Health Care Directive or in a Medical Power of Attorney)
- Spouse
- Adult child (18 years of age or over) for his or her parent
- Parent for an adult child
- An adult sibling
- A grandparent for an adult grandchild
- An adult grandchild (18 years of age or older) for a grandparent

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