

## Legally Authorized Representative (LAR): Use of Surrogate Consent in Research

*This guidance document is intended for investigators planning to conduct human subjects research that involves the use of surrogate consent for adult subjects. Should you need additional assistance, please contact OPHS at 510-642-7461 or [ophs@berkeley.edu](mailto:ophs@berkeley.edu).*

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### A. Background

Federal regulations permit investigators to obtain consent from a legally authorized representative (LAR) in research that involves enrollment of prospective research subjects who cannot provide consent on their own behalf. The California [Health & Safety Code 24178](#) and the [University of California Guidance on Surrogate Consent for Research](#) describe who may serve as an LAR in research. The state law uses the term “surrogate decision-maker” or simply “surrogate” to refer to the LAR.

### B. Definitions

#### Legally Authorized Representative (LAR)

Per Federal regulations, LAR means “an individual, or judicial, or other body authorized under applicable law to consent on behalf of a prospective research subject to the subject’s participation in the procedure(s) involved in the research” (45 CFR 46.102(c) and 21 CFR 50.3(l)).

The [2018 Revised Common Rule](#) provided clarification to supplement this definition. Specifically, “in jurisdictions where there is no applicable law for allowing an LAR to provide consent on behalf of a prospective research subject, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective research subject to the subject’s participation in the procedure(s) involved in the research” (45 CFR 46.102(i)).

#### Surrogate Consent

In research, surrogate consent is the use of an LAR, with reasonable knowledge of the research subject, who shall include any of the persons, in descending order of priority as described in Section D.a. below.

#### Advanced Healthcare Directive

Documents written in advance of serious illness in which a person states their choices for healthcare or names someone to make those choices. When a person is selected to make medical decisions, the document is called a Durable Power of Attorney and the designated person is called an Agent. The Agent can serve as an LAR to provide surrogate consent for participation in research.

**Capacity to Consent (to Research)**

The ability of the individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision (e.g., whether or not to participate in a study).

**Medical Experiment:**

The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject. ([California Health and Safety code 24174](#))

**C. Determining Whether Use of Surrogate Consent is Appropriate**

Consistent with California State Law, CPHS uses the following criteria when determining whether to allow the use of surrogate consent for participation in a research study:

- The research subject is unable to consent and does not express dissent or resistance to participation. Whenever possible, investigators should attempt to obtain informed consent directly from the research subject;
- The research subject is not:
  - (i) An inpatient on a psychiatric unit or in a mental health facility; or
  - (ii) A patient on a psychiatric hold (in accordance with California Health & Safety Code § 24178(j));
- The research involves “medical experimentation;” and
- The medical experiment relates to cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subjects.

In the event that a research subject may qualify for surrogate consent, investigators should include the following in the eProtocol application for review by CPHS:

- A protocol-specific plan for assessment of the decision-making capacity by the investigator (see [Appendix 1](#)) of any research subject who may require the consent of a legally authorized representative, including:
  - Whether the participants may have a medical condition that may render them temporarily or permanently unable to provide informed consent and/or cognitive impairments such as intellectual disability, dementia, or psychosis;
  - The criteria for identifying participants who may be unable to consent;
  - Who will conduct the assessment for decisional capacity; and
  - The method by which capacity will be evaluated.
- A [Decision-Making Capacity Assessment Tool](#) is available for investigators to assess the understanding of the consent process of subjects who may have cognitive impairments, or may elicit the information using clinical interview procedures. CPHS may permit less formal procedures to assess capacity (e.g. assessment of capacity through routine interactions with the participant) when the study is no more than minimal risk.

**D. Identifying an Appropriate Surrogate/Legally Authorized Representative**

In California, [Health and Safety Code 24178](#) describes who may serve as an LAR to give consent for a prospective research subject who cannot provide consent on their own behalf. An LAR is prohibited from receiving financial compensation for providing consent.

a. In a **non-emergency room environment**, surrogate consent may be obtained from any of the following potential surrogates who have reasonable knowledge of the research subject in the following descending order of priority:

- (1) The agent named in the potential research subject's advance health care directive.
- (2) The conservator or guardian of the potential research subject, with authority to make healthcare decisions for the potential subject.
- (3) The spouse of the potential research subject.
- (4) The registered domestic partner of the potential research subject as defined in [Section 297 of the Family Code](#).
- (5) An adult son or daughter of the potential research subject.
- (6) A custodial parent of the potential research subject.
- (7) An adult brother or sister of the potential research subject.
- (8) An adult grandchild of the potential research subject.
- (9) An available adult relative with the closest degree of kinship to the potential research subject, whose relationship to the potential subject does not fall within one of the above listed categories, and which relationship can best be described as (e.g., aunt; uncle; cousin; etc.).

***Important Notes:***

The investigator is responsible for making a reasonable effort to determine if that individual is available to serve as an LAR. A potential LAR must be advised that if a higher-ranking surrogate is identified at any time, the investigator will defer to the higher-ranking surrogate's decision regarding the subject's participation in the research. When there are two or more available persons who may provide surrogate consent and who are in the same order of priority (e.g., an adult son and daughter of the potential participant), if any of those persons in the same order of priority expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

The investigator must document the LAR's relationship to the potential research participant using the [Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research Form](#).

b. In an **emergency room environment**, the order of priority does not apply, nor does the surrogate have to show reasonable knowledge of the research subject. Surrogate consent may be obtained from any of the following:

- (1) The agent named in the potential research subject's advance health care directive.
- (2) The conservator or guardian of the potential research subject, with authority to make healthcare decisions for the potential subject, or the spouse of the potential subject.
- (3) The spouse of the potential research subject.
- (4) The registered domestic partner of the potential subject as defined in Section 297 of the California Family.
- (5) An adult son or daughter of the potential research subject.
- (6) A custodial parent of the potential research subject.
- (7) Any adult sibling of the potential research subject.

***Important Notes:***

In an emergency room environment, no surrogate may be utilized if there is a disagreement whether to consent among any available surrogates.

The investigator must document the LAR's relationship to the potential research participant using the [Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research Form](#).

## **E. Obtaining Surrogate Consent from an LAR**

### **Initial Consent**

If the research subject is responsive but lacks the capacity to consent, the investigator must make a reasonable effort to describe the research to the subject in a manner consistent with the standard consent process and indicate the intent to obtain surrogate consent. This communication should be documented in the research file. If, however, the research subject is non-responsive (e.g., unconscious due to trauma or medication administered to treat that trauma), the investigator will document this observation in the research file, and a note in the participant's medical record that references the research file.

If the research subject expresses resistance or dissent to being in the research or to the use of the surrogate consent by word or gesture, they will be excluded from the research study.

### **Ongoing Consent:**

Consent in research is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study shall apply to research subjects whose consent has been provided by an LAR. In addition, researchers must also be prepared to re-evaluate a subject's ability to consent over time:

- In cases where the subject regains the cognitive ability to consent, the research subject must be re-consented using the standard consenting process as soon as possible. After re-consent, the consent previously granted by the LAR is no longer considered valid. If in the re-consenting process, the research subject indicates that s/he no longer wish to continue participation, the subject must be withdrawn from study in a safe and respectful manner.
- In the event that a research subject has been initially consented by an LAR, and a surrogate of higher priority subsequently notifies the investigator of that relationship to the research subject, the investigator must defer to the higher priority surrogate's decision regarding whether the research subject will continue to participate or to withdraw from the study.
- Investigators must describe to potential surrogates the nature of ongoing decisions during the study, including decision to participate in certain procedures, changes to the study, etc., in order to ensure that the surrogate will be willing to undertake these ongoing responsibilities.
- In the event that the LAR dies, the research subject or next available surrogate must be re-consented upon any event that would otherwise trigger re-consenting the research subject.

A new [Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research Form](#) must be completed if the previously identified surrogate becomes unavailable or a surrogate of a higher priority is identified.

In conformance with the [Common Rule](#), for research that is no more than minimal risk, CPHS may approve a request to waive some or all of the required elements of informed consent under specific criteria, and in such cases the need for surrogate consent may also be waived.

### **No Financial Compensation:**

A surrogate decision-maker is prohibited from receiving financial compensation for providing consent. Cal. Health & Safety Code 24178.

## **F. Resources**

[UCOP Guidance on Surrogate Consent for Research](#)

[Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research Form](#)

[UCLA Decision-Making Capacity Assessment Tool](#)

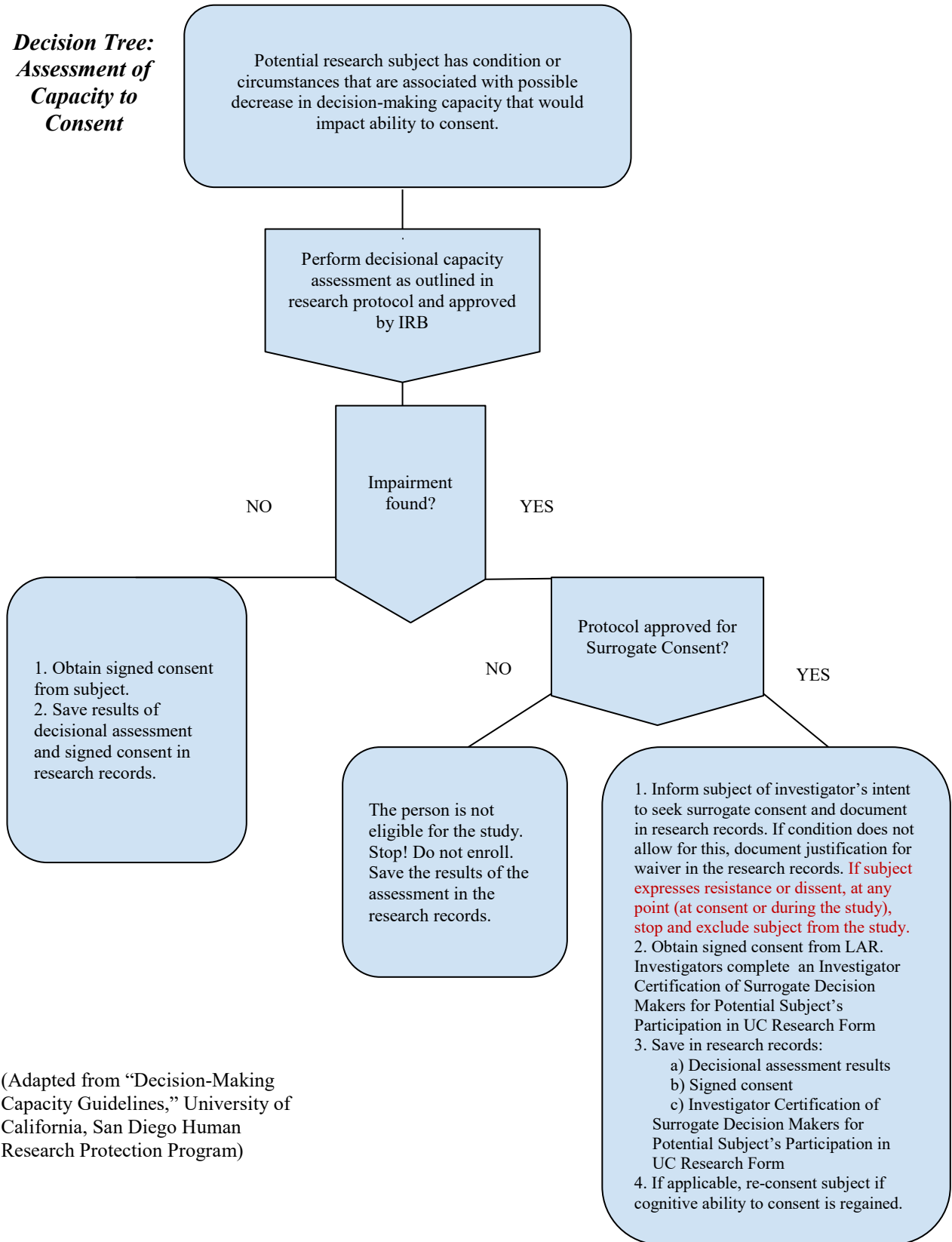
[Revised Common Rule Q&As - Definition of Legally Authorized Representative](#)

[Refer to 45 CFR 46.102(i) the [revised Common Rule](#).]

[California Health and Safety Code 24178; California Health and Safety Code 24174](#)

### Appendix 1

#### ***Decision Tree: Assessment of Capacity to Consent***



(Adapted from “Decision-Making Capacity Guidelines,” University of California, San Diego Human Research Protection Program)