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.

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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 a LAR in research. The state law uses the terms “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 a 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 C.F.R. § 46.102(i)
Surrogate Consent

In research, surrogate consent is the use of a LAR, with reasonable knowledge of the research subject, who shall include any of the persons, in descending order of priority, described under California law (Health & Safety Code 24178).

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 the medical decisions, the document is called a Durable Power of Attorney and the designated person is called an Agent. The Agent can serve as a 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).

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:

- Surrogate consent may be permitted by CPHS only in research studies relating to cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subjects.
- Whenever possible, investigators should attempt to obtain informed consent directly from the research subject.
- 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 rationale for the use of surrogate consent (e.g., subjects may have a medical condition that may render them temporarily unable to provide informed consent and/or cognitive impairments such as dementia, mental retardation, etc.);
  - A protocol-specific plan for assessment of the decision-making capacity (see Appendix 1) of any research subject who may require the consent of a legally authorized representative. In the plan, describe the process/formal evaluation of how the decision-making capacity will be assessed and by whom. A decision-making capacity tool is available for assessing competency to provide informed consent.

Important Note: Surrogate consent to participate in research is not permitted in a State of California mental health facility, inpatient psychiatric wards, or with persons on psychiatric hold.
D. Identifying an Appropriate Surrogate/Legally Authorized Representative

In California, Health and Safety Code 24178 describes who may serve as LAR to give consent for a prospective research subject who cannot provide consent on their own behalf.

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 subject’s advance health care directive.
(2) The conservator or guardian of the potential subject, with authority to make healthcare decisions for the potential subject.
(3) The spouse of the potential subject.
(4) The registered domestic partner of the potential subject as defined in Section 297 of the Family Code.
(5) An adult son or daughter of the potential subject.
(6) A custodial parent of the potential subject.
(7) An adult brother or sister of the potential subject.
(8) An adult grandchild of the potential subject.
(9) An available adult relative with the closest degree of kinship to the potential 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:

● In non-emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among the members of the highest available priority class of surrogates, (e.g., where two members of persons in the highest of categories (5) - (7) disagree and there is no person in categories (1) - (4) available.

● In non-emergency room research settings only, the investigator is responsible for ensuring that the surrogate:
  ➢ Has reasonable knowledge of the potential subject;
  ➢ Is familiar with the subject's degree of impairment;
  ➢ Is willing to serve as the substitute decision-maker;
  ➢ Understands the risks, potential benefits, procedures and available alternatives to research participation;
  ➢ Makes decisions based on the potential subject’s known preferences, and where the subject's preferences are unknown, makes decisions based upon the surrogate's judgment of what the subject's preferences would be.
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 subject’s advance health care directive.
2. The conservator or guardian of the potential subject, with authority to make healthcare decisions for the potential subject, or the spouse of the potential subject.
3. The registered domestic partner of the potential subject as defined in Section 297 of the California Family.
4. An adult son or daughter of the potential subject.
5. A custodial parent of the potential subject.
6. Any adult brother or sister of the potential subject.

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

E. Obtaining Surrogate Consent from a LAR

a. **Initial Consent**

If the research subject is responsive but lacks the capacity to consent, the investigator will 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 the discussion described above regarding intent to seek surrogate consent will be waived.

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, s/he will be excluded from the research study.

The appropriate LAR shall complete the “**Self-Certification of Surrogate Decision Makers for Potential Subject’s Participation in Research**” form as an attachment to the informed consent document for the research study. The “Self-Certification of Surrogate Decision Makers for Participation in Research” form verifies the willingness of the person to serve as a LAR, details the relationship of the LAR to the subject, and the LAR’s qualifications demonstrating “reasonable knowledge” of the research subject. (Note: Section 3 of the “Self-Certification of Surrogate Decision Makers for Participation in Research” form is required only for surrogate consent in non-emergency room environment settings.)

b. **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 subjects whose consent has been provided by a 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 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 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 subject has been initially consented by a surrogate, and a surrogate of higher priority subsequently notifies the investigator of that relationship to the subject, the investigator must defer to the higher priority surrogate’s decision regarding whether the subject will continue to participate or to withdraw from the study.

F. Resources

UCOP Guidance on Surrogate Consent for Research

Self-Certification of Surrogate Decision Makers for Potential Subject’s Participation in University of California Research

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
Appendix 1

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

Potential research subject has condition or circumstances that are associated with possible decrease in decision-making capacity that would impact ability to consent.

Perform decisional capacity assessment as outlined in research protocol and approved by IRB

- **Impairment found?**
  - NO
  - YES

   1. Obtain signed consent from subject.
   2. Save results of decisional assessment and signed consent in research records.

- Protocol approved for Surrogate Consent?
  - NO
  - YES

  1. Inform subject of investigator’s intent to seek surrogate consent and document in research records. If condition does not allow for this, document justification for waiver in the research records. If subject expresses resistance or dissent, at any point (at consent or during the study), stop and exclude subject from the study.
  2. Obtain signed consent from legally authorized representative (LAR). Have LAR complete Self-Certification form.
  3. Save in research records:
     a) Decisional assessment results
     b) Signed consent
     c) Self-Certification form
  4. If applicable, re-consent subject if cognitive ability to consent is regained.

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