

Guidance: Use of Legally Authorized Representative (Surrogate Consent)

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Introduction

This guidance provides investigators with information on the measures that need to be taken and the required documentation when they plan to enroll prospective research participants who cannot consent on their own behalf.

Federal regulations permit investigators to obtain consent from a legally authorized representative. California law ([Health & Safety Code 24178](#)) and [UC Guidance on Surrogate Consent for Research](#) define the categories of individuals who are allowed to provide surrogate consent for research.

This guidance applies to the following groups:

- Individuals whose medical condition may render them temporarily unable to provide informed consent as a consequence of severe pain, confusion, or impaired consciousness due to events such as life-threatening illness or trauma, and
- Individuals who have cognitive impairments such as intellectual disabilities, dementia, or psychosis that are enduring or that may worsen with time

There are separate informed consent guidelines for [planned research in emergency settings](#) and for [research involving children and minors](#) and are described in separate guidance documents.

Definitions

Legally Authorized Representative (LAR): An individual or judicial, or other body authorized under applicable law to grant permission on behalf of a prospective participant for their participation in research activities.

Surrogate Consent: The use of a legally authorized representative with reasonable knowledge of the research participant, who shall include any of the persons, in descending order of priority, described under California law ([Health & Safety Code 24178](#)).¹

¹ At UCLA, surrogate consent was previously referred to as “proxy consent.”

Advance 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.

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).

Criteria for Use of Surrogate Consent

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

- Surrogate consent may be permitted by the IRB **only** in research studies relating to cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research participants.
- Investigators must include the following in the application for review by the IRB:
 - **A protocol-specific plan** for assessment of the decision-making capacity by the investigator of any research participants who may require the consent of a legally authorized representative.
 - **If the research participant lacks capacity to consent**, the investigator will describe the research to the participant in a manner consistent with the standard consent process and indicate the intent to obtain surrogate consent. Note: This communication should be documented in the research record. If, however, the research participant is non-responsive, 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 participant 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.

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.

Determining Capacity to Consent

Whenever possible, investigators should attempt to obtain informed consent directly from the research participant.

In the event participants may qualify for surrogate consent, the **IRB application should specify/describe:**

- Whether the participants may have medical condition may render them temporarily unable to provide informed consent and/or cognitive impairments such as mental retardation, 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.

While there are no standardized measures for determining capacity to consent, **participants should be assessed on their abilities to understand** and to express a reasoned choice concerning the:

- Nature of the research and the information relevant to his/her participation;
- Consequences of participation for their own situation, especially concerning their health condition; and
- Consequences of the alternatives to participation.

Important Note: Investigators may use the [UCLA Decision-Making Capacity Assessment Tool](#) to assess the understanding of the consent process of persons who may have cognitive impairments, or may elicit the information using clinical interview procedures. The IRB 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. For additional guidance on assessment of capacity to consent with individuals who have cognitive impairments refer to [OHRPP Guidance: Research Involving Persons with Cognitive Impairments](#).

Identifying an Appropriate Surrogate

[California Law](#) specifies who may serve as surrogates in non-emergency and emergency settings as follows:

- In a **non-emergency room** environment, surrogate consent may be obtained from any of the following potential surrogates who have reasonable knowledge of the participant, in the following descending order of priority:
 - The person's agent designated by an advance health care directive.
 - The conservator or guardian of the person having the authority to make health care decisions for the person
 - The spouse of the person
 - The domestic partner of the person as defined in [Section 297 of the California Family Code](#)
 - An adult son or daughter of the person.
 - A custodial parent of the person.
 - Any adult brother or sister of the person
 - Any adult grandchild of the person
 - An available adult relative with the closest degree of kinship to the person.

Important Notes:

- When there are two more available persons available to serve as surrogates, the decision of the person with the highest priority, as determined by the list above, takes precedence and cannot be superseded by the consent of a person with lower priority.
- If there are two or more potential surrogates with the same priority - and it is the highest priority available – disagree about participation in the research, then consent for the research **cannot** be given. For example, if an adult son and daughter disagree about their father's participation in a study (category 5) and none of the persons listed in categories (1) through (4) are available, then the father cannot be in that study.
- In *non-emergency* settings, only, investigators are responsible for ensuring that the surrogate:
 - Has reasonable knowledge of the research participant;
 - Is familiar with the participant'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 research participant's known preferences, and where the preferences are unknown, makes decisions based upon the surrogate's judgment of what the subject's preferences would be.

- In an **emergency room setting**, the order of priority does not apply, not does the surrogate have to show reasonable knowledge of the research participant. Surrogate consent may be obtained from any of the following:
 - The person’s agent designated by an advance health care directive.
 - He conservators or guardian of the person having the authority to make health care decisions for the person.
 - The spouse of the person.
 - The domestic partner of the person as defined in [Section 297 of the California Family Code](#)
 - An adult son or daughter of the person.
 - A custodial parent of the person.
 - Any adult brother or sister of the person.

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

Obtaining Consent from the Surrogate

The following apply when obtaining consent from a surrogate:

- Potential surrogates should be told the nature of ongoing decisions during the study regarding the subject’s participation, decision to participate in certain procedures, changes to the study, and other aspects of the study to ensure that the surrogate will be willing to undertake these ongoing responsibilities
- Surrogates should complete the [Self Certification of Surrogate Decision Makers for Potential Subject Participation in University of California Research](#) as an attachment to the informed consent document for the research study, and be given a copy of this form along with a copy of the consent to keep. In addition, investigators must keep a copy of the signed form in the research records with the signed consent. If consent is completed remotely under a waiver of signed informed consent, this self-certification form may also be completed remotely without signature.

Important Note: Section 3 of this form is required only for surrogates in non-emergency room settings.
- A surrogate’s decision making capacity should be assessed only when the investigator has reason to believe that the surrogate’s decision-making capacity may be impaired.
- Surrogates are prohibited from receiving any financial compensation for providing consent. This does not prohibit the surrogate from being reimbursed for expenses the surrogate may incur related to the surrogate’s participation in the research.
- In **non-emergency settings**: Potential surrogates 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) of higher degree of surrogacy, the investigator is responsible for contacting this person(s) to determine if s/he wants to serve as surrogate.

Initial Consent and Consent on an Ongoing Basis

Consent documents should address the person who is most likely to provide initial consent for the study.

Person(s) to be Consented	Consent Form
The study will likely enroll participants who are able to consent for themselves as well as those who will need a legally authorized representative.	Address the consent form to the participant. Include a signature line for the legally authorized representative with a space to

	indicate the relationship to the participant
The study will only enroll participants who will need legally authorized representatives to provide consent.	Address the consent form to the legally authorized representative.

Consent is an ongoing process. All applicable criteria that would trigger re-consent of a research participant in any study also applies to participants whose consent has been provided by a surrogate. In addition:

- ***A research participant who regains the cognitive ability to consent*** must be re-consented using the standard consenting procedure and offered the options listed below. These options should be included in the initial consent form
 - Remain in the study
 - Withdraw from the study and allow use of collected data/specimens
 - Withdraw from the study, including withdrawal of collected data and specimens from further research use. Please note: Data already collected must be retained if the study is FDA-regulated or required by the terms of the funding agreement.
- In the event a research participant has been initially consented by a surrogate, and ***a surrogate of higher priority subsequently notifies the investigator of that relationship to the subjects***, 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.
- ***In the event that the surrogate dies***, a new surrogate must be identified.

The following versions of consent forms will be needed:

- One for the surrogate
- One for the participant if he or she regains capacity to consent. This one should allow for
 - Person to continue in study.
 - Person not to continue in study and to explain that data collected so far will be used for research purposes.
 - Person not to continue in the study but to request that data already collected not be used. Please note: Data already collected must be retained if the study is FDA-regulated or required by the terms of the funding agreement.

Research Conducted Outside California

The identification of legally authorized representatives depends on the laws and regulations of the local jurisdiction. When investigators plan on enrolling research participants outside California, they should check with UCLA legal counsel regarding the local surrogate consent laws. The following information should be included in the IRB application:

- Information on the local laws/regulations regarding surrogate consent and relevant citations, and
- A description of the procedures that will be used to obtain consent from legally authorized representatives consistent with local requirements.

Change history:

6/9/2016: Clarifications to outline acceptable remote use of Self Certification form, without signature; highlighted data retention requirements of FDA/sponsor; that new surrogate must be identified in event surrogate dies.