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## Title: Obtaining Surrogate Consent – The Basics

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Audience: Researchers Utilizing the Surrogate Consent Process

This guidance provides researchers with information about how to enroll prospective research subjects who cannot consent on their own behalf. Federal regulations permit researchers 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.

Use of Surrogate Consent is specific to two groups of prospective subjects:

- ✓ 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

Note: There are separate informed consent requirements for planned research in emergency settings and for research involving children.

The following are the basic steps for obtaining surrogate consent:

### The Researcher:

- ✓ Confirm that the IRB has granted approval for the use of Surrogate Consent by reviewing the IRB Approval letter
- ✓ When possible, attempt to obtain informed consent directly from the prospective subject
- ✓ Determine capacity to consent - *Note: Researchers may use the [Decision Making Capacity \(DMC\) Assessment Tool](#) to assess the understanding of the consent process of prospective subjects who may have cognitive impairments, or may elicit the information using clinical interview procedures*
- ✓ Identify an appropriate surrogate; [California Law](#) specifies who may serve as surrogates in non-emergency room and emergency room settings
- ✓ Potential surrogates must be advised that if a higher-ranking surrogate is identified at any time, the researcher will defer to the higher-ranking surrogate's decision regarding the subject's participation in the research
- ✓ For non-emergency room setting only, if the potential surrogate identifies a person of a higher degree of surrogacy, the researcher is responsible to contact such individuals to determine if they want to serve as surrogate
- ✓ Ensure that the surrogate identified has reasonable knowledge of the subject; is familiar with the subject's degree of impairment, and is willing to serve as the substitute decision-maker
- ✓ Confirm that the surrogate understands the risks, potential benefits, procedures and available alternatives to research participation
- ✓ Assure, to the best of the researcher's ability, that the surrogate's decisions are based on the 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 if different from their own

### The Surrogate Decision Maker:

- ✓ Complete the [Self-Certification of Surrogate Decision Makers for Participation in Research](#) form
- ✓ Sign and date the informed Consent Form
- ✓ Receive a copy of the signed informed Consent Form
- ✓ Are prohibited from receiving any financial compensation for providing consent - *Note: This does not prohibit the surrogate from being reimbursed for expenses the surrogate may incur related to the surrogate's participation in the research*



**The Research Record must include:**

- ✓ The original (preferred) or a copy of the signed Consent Form
- ✓ A copy of the completed *Self-Certification of Surrogate Decision Makers Participation in Research* form

**Reminders:**

- ✓ ***Consent is an ongoing process.*** All applicable criteria that would trigger re-consent of a research subject in any study also applies to subjects whose consent have been provided by a surrogate.
- ✓ ***A research subject who regains the cognitive ability to consent*** must be re-consented using the standard consenting procedures.
- ✓ ***If a surrogate of higher priority is later identified,*** the researcher must defer 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,*** the subject must be re-consented subsequent to any event that would otherwise trigger re-consenting the subject.

