Surrogate Consent Reminders for Investigators

The California Health & Safety Code Section 24178 of the Medical Experimentation Act was modified on January 1, 2003. Specific individuals can provide surrogate informed consent for the enrollment of adult subjects who lack capacity to consent for medical experiments that “relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of participants.”

Informed Consent and Decision-Making Capacity Assessment Reminders:

- Prior IRB approval is required for the use of surrogate consent.

- The presence of a cognitive impairment should not lead to the presumption that a person is incapable of deciding on their participation in research

- Investigators must attempt to obtain informed consent directly from the subject

- If an investigator suspects that the subject lacks the capacity to consent, a decision-making capacity assessment must be conducted.

- The UCI HRP has a suggested Decision Making Capacity Tool that can be used.

- While there are no standardized measures for determining capacity to consent, subjects may 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 the subject’s own situation, especially concerning the subject’s health condition; and
  - Consequences of the alternatives to participation

- If it is determined that the subject lacks the capacity to consent, the investigator must inform the subject of the investigator’s intent to seek surrogate consent and must document this discussion in the research file/chart.

- If the subject expresses resistance or dissent to participation or to the use of surrogate consent, the subject is excluded from the research study.
Obtaining Consent from the Surrogate:

Surrogate consent may be obtained from any of the following potential surrogates who has reasonable knowledge of the subject, in the following descending order of priority:

- The person’s agent identified by an advance health directive
- the conservator or legal guardian of the person having the authority to make health care decisions for the person;
- the spouse
- the domestic partner
- an adult son or daughter
- a custodial parent
- any adult sibling

The remaining selections may only be utilized in non-emergency room settings, as specified in California Health & Safety Code Section 24178:

- any adult grandchild
- the closest adult relative available

Notes:

- The Investigator must attempt to find the person highest in the order of priority who agrees to be the surrogate.
- The subject should not determine their own surrogate.
- 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.
- If two or more available surrogates in the same order of priority disagree, consent is considered not to have been given.
- If two or more available persons who are in different orders of priority disagree, the higher priority person shall not be superseded by the lower priority person.
- If the potential surrogate identifies a person of a higher degree of surrogacy, the investigator is responsible to contact such individuals to determine if they want to serve as surrogate.
- 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 participation in the research.
- 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.
The Investigator is responsible to ensure that the surrogate:

- Has reasonable knowledge of the 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 their decisions 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.

To help address the above requirements, the Investigator will:

- Complete the [Investigator Certification of Surrogate Decision Makers for Potential Subject’s Participation in University of California Research](#)
- Provide the surrogate with the informed consent form
- Give the individual adequate opportunity to read, review and consider the research and alternative options
- Respond to the surrogate's questions, ensuring that the surrogate has comprehended this information
- Obtain the surrogate's consent