Guidance for USD Researchers Seeking Surrogate Consent

When an individual lacks the capacity to consent to participation in research, federal regulations permit researchers to obtain consent from a legally-authorized representative. California Health & Safety Code 24178 defines the categories of individuals who are legally authorized in California to provide surrogate consent for research. In order for researchers to obtain consent from a subject's legally-authorized representative, ***the University of San Diego (USD) Institutional Review Board (IRB) must approve the use of Surrogate Consent.*** The following protocol is based on the University of California Office of Research Policy Analysis & Coordination, Guidance Memo 21-01 (2021) available at: https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0yMS0wMQ==&doc=3789

I. Surrogate Consent in Non-Medical Research

It is anticipated that most researchers at USD will be seeking Surrogate Consent for research that is not defined as "medical experimentation" (see 3(b) below.) While California state law addresses surrogate consent **only** in the context of medical research, the **same** surrogates in priority order authorized by Section 24178 will also be considered for providing consent in the context of non-medical research. (See Section V(A) (1-8) below for a list of surrogates in priority order.) In conformance with the Common Rule, for research that is no more than minimal risk the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances.

II. Surrogate Consent in Medical Research

California Health and Safety Code Section 24178 specifies that surrogate consent may be permitted only when the following conditions are met in medical research:

1. The research participant is unable to consent and does not express dissent or resistance to participation;
2. The research participant is not:
    a. An inpatient on a psychiatric unit or in a mental health facility; or
    b. A patient on a psychiatric hold (in accordance with California Health & Safety Code Section 24178(j);
3. The research involves "medical experimentation", AND
    a. The medical experiment relates to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants.
    b. "Medical Experimentation" is defined in California Health & Safety Code Section 24174 as: (a) 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 the subject or otherwise directly benefiting the subject; or (b) The investigational use of a drug or device; or (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

III. IRB Application Information for Researchers

For the use of surrogate consent in research, investigators must include the following in their application for review to the USD 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, 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.
- If the research participant lacks capacity to consent, the investigator must make a reasonable effort to describe the research to the participant in a manner consistent with the standard consent process and indicate the intent to obtain surrogate consent.
- If the research participant expresses resistance or dissent to participating in the research or to the use of the surrogate consent by word or gesture, they must be excluded from the research study.

IV. Assessing the Decision-Making Capacity of the Participant

While currently 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 following:

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

USD researchers may use (with appropriate citation) the University of California 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.

V. Categories of Potential Surrogate: Who May Serve as a Surrogate Decision Maker

California Health & Safety Code Section 24178 describes who may serve as a surrogate decision maker – in a **non-emergency room setting** and in an **emergency room** – when a research participant cannot provide consent on their own behalf.*

* Note that the requirements regarding who may serve as a surrogate described in this Guidance Memo do not apply to participants who lack capacity to give informed consent and who are: (1) involuntarily committed the California Welfare and Institutions Code § 5000 et seq.;

or (2) voluntarily admitted or have been admitted upon the request of a conservator pursuant to the California Welfare and Institutions Code § 6000 et seq. Cal. Health & Safety Code § 24178(j).

A. Non-Emergency Room Environment

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 participant, in the following descending order of priority:

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

The investigator is responsible for making a reasonable effort to determine if that individual is available 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. 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. California Health & Safety Code § 24178(d)).

The investigator must *document the surrogate's relationship* to the potential research participant using the Investigator **Certification of Surrogate Decision Makers for Potential Subject's Participation in Research at USD Form**

Emergency Room Environment

In an emergency room setting, under law, *the order of priority does not apply,* nor does the surrogate have to show reasonable knowledge of the subject. Surrogate consent may be obtained from a surrogate decision maker who is any of the following: 1. The agent named in the potential research participant's advance health care directive. 2. The conservator or guardian of the potential research participant, with authority to make healthcare decisions for the potential participant. 3. The spouse of the potential research participant. 4. The registered domestic partner of the potential research participant as defined in Section 297 of the Family

Code. 5. An adult child of the potential research participant. 6. A custodial parent of the potential research participant. 7. An adult sibling of the potential research participant.
In emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.

Re-consenting Research Participants Consent is an ongoing process.
All applicable criteria that trigger re-consenting a participant in any study apply to research participants whose consent has been provided by a surrogate. In addition:

- A participant who regains the cognitive ability to consent must be re-consented using standard consenting procedures.
- In the event a participant has been initially consented by a surrogate, and a surrogate of higher priority subsequently notifies the investigator of that relationship to the research participant, the investigator must defer to the higher priority surrogate's decision regarding whether the research participant 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 surrogate dies, or can no longer serve in the surrogate's capacity, the participant or next available surrogate must be re-consented upon any event that would otherwise trigger re-consenting the participant.

Notes:

- Investigators must complete a new Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in USD Research Form if the previously identified surrogate becomes unavailable or a surrogate of a higher priority is identified.
- Additional Requirements of the Surrogate Substitute Judgment California law requires that surrogate decision makers "exercise substituted judgment, and base decisions about participation in accordance with the [participant's] individual health care instructions, if any, and other wishes, to the extent known to the surrogate decisionmaker." Otherwise, the surrogate decision maker must make the decision "in accordance with the [participant's] best interests." In determining the participant's best interests, the decision maker must consider the person's personal values, using a best estimation of what the person would have chosen if the participant were capable of making a decision. Cal. Health & Safety Code § 24178(g)

No Financial Compensation
A surrogate decision-maker is prohibited from receiving financial compensation for providing consent. Cal. Health & Safety Code § 24178(i).