UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Submitting or Amending a Protocol to Include the Option of Surrogate Consent

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California law AB2328, codified as California Health & Safety Code Section 24178 became effective January 1, 2003 and clarifies who may serve as a research subject's "legally authorized representative." Surrogate consent for participation in a research study should be employed only to the extent that it is consistent with federal and state laws and guidance pertaining to protecting human subjects participation in research. Consistent with guidelines provided by the University of California Office of the President (available on the HRPP website at http://irb.ucsd.edu/surrogate.shtml) the IRB will use the following criteria when determining whether to permit the use of surrogate consent for participation in a research study:

- Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research subject.
- The investigator shall include in the IRB application/modification form a protocol-specific plan for the sequence of steps that will be employed to acquire and document surrogate consent provided by a legally authorized representative.
- Because these types of protocol amendments will always be considered major amendments and require full review by a convened IRB committee, a revised Research Plan and FaceSheet should be downloaded from the HRPP website and used for the submission of the amendment. The plan for obtaining Surrogate Consent is Item 28 in the Biomedical Application.

The text of the instructions for completing that section of the application are reproduced here, as the requirements of California law apply also to social and behavioral science research that is of a nonmedical nature.

Steps required by California AB2328 for obtaining Surrogate Consent

1. Whenever possible, investigators will attempt to obtain informed consent directly from the subject.
2. If the potential research subject is obtunded, unconscious or otherwise obviously lacking in decision-making capacity, the investigator shall:
    a) Document that observation in the research record and in the subject's medical record;
    b) Proceed with the steps listed below under *Identifying Persons to Provide Surrogate Consent*
3. If the potential research subject has questionable capacity to consent but is not unresponsive, the investigator shall:
    a) Consistent with the standard consent process, describe the research to the subject;

b) Perform and document an assessment of the participant's decisional-capacity relevant to the information provided about the research study (see UCSD Procedures for Decisional Capacity Assessment for various approaches to doing this step. Include in this section of the application which of the approaches available will be employed by this study);
c) If lack of decisional capacity is evident, the investigator shall inform the potential research subject of the investigator's intent to obtain surrogate consent;
d) If the subject expresses resistance or dissent to participation or to the use of surrogate consent by word or gesture, the subject shall be excluded from the research study.
e) If no resistance or dissent is expressed by the potential research subject, the investigator shall document this fact, and document that the description of the research project was communicated to the subject by placing a note in the medical record and in the research record.
f) Proceed with the steps listed below under *Identifying and Informing Persons providing Surrogate Consent*

Identifying Persons to Provide Surrogate Consent

In a non-emergency room environment, 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:

1. The person's agent designated by an advance health care directive.
2. The conservator or guardian of the person having the authority to make health care decisions for the person.
3. The spouse of the person.
4. The domestic partner of the person as defined in Section 297 of the Family Code
5. An adult son or daughter of the person.
6. A custodial parent of the person.
7. Any adult brother or sister of the person.
8. Any adult grandchild of the person.
9. An available adult relative with the closest degree of kinship to the person.

. 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 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 if different from their own.

In an emergency room setting, 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 person's agent designated by an advance health care directive.
2. The conservator or guardian of the person having the authority to make health care decisions for the person.
3. The spouse of the person.
4. The domestic partner of the person as defined in Section 297 of the Family Code.
5. An adult son or daughter of the person.
6. A custodial parent of the person.
7. Any adult brother or sister of the person.

In emergency room research settings, *no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.*

Obtaining Consent from the Surrogate

1. Investigators shall describe to potential surrogates the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures, changes to the study, etc., in order to ensure that the surrogate will be willing to undertake these on-going responsibilities.
2. The surrogate shall complete the "*Self-Certification of Surrogate Decision Makers for Participation in Research*" form 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, the researcher must keep the signed form in the research records along with the signed consent. The "*Self-Certification of Surrogate Decision Makers for Participation in Research*" form verifies the willingness of the person to serve as a surrogate, details the relationship of the surrogate to the subject and the surrogate'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).
3. 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.
4. For non-emergency room environment research only, 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.

5. 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.

6. Assessment of the decision-making capacity *of the surrogate* should be implemented only when the investigator has reason to believe that the surrogate's decision-making capacity may be impaired.

NOTE: Surrogate consent to participate in research under California Health & Safety Code section 24178 **is not permitted** for persons on an inpatient psychiatric ward, inpatients of a mental health facility, or persons on psychiatric hold. This is more restrictive than the standard under previously existing law whereby an incapacitated adult with a conservator or guardian could be enrolled onto a study being conducted in an inpatient psychiatric unit because conservators and guardians were considered legally-authorized representatives.

Re-consenting of Research Subjects

Consenting 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 surrogate. In addition:

- A subject who regains the cognitive ability to consent must be re-consented using standard consenting procedures.
- In the event 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.
- Investigators shall describe to potential surrogates the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures, changes to the study, etc., in order to ensure that the surrogate will be willing to undertake these on-going responsibilities.

In the event that the surrogate dies, the subject must be re-consented subsequently upon any event that would otherwise trigger re-consenting the subject.

Questions

Questions regarding Decisional Capacity Assessment and Surrogate Consent should be directed to the UCSD Human Research Protections Program office at 858-455-5050, or by e-mail to hrpp@ucsd.edu.