

UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT OFFICE OF RESEARCH

GUIDANCE ON SURROGATE CONSENT FOR RESEARCH

Implementation of Procedures for Obtaining Surrogate Consent to Adult Subjects' Participation in Research Relating to the Subject's Cognitive Impairment, Lack of Capacity, or Serious or Life-Threatening Disease

Effective January 1, 2003

Preamble

Cognitive disorders that produce great suffering and stigmatization present an area of biomedical and behavioral science in which new approaches to treatment are showing great promise. Accordingly, research that involves persons with disorders or physical traumas that impair cognition is an important and growing scientific endeavor. As a result, it is anticipated that persons with cognitive impairments may be recruited as subjects of research studies, the outcomes of which can make significant contributions to the welfare of society. Special protections are essential to guide research involving such vulnerable persons, but it is also critical to acknowledge that ethical harm may result by excluding persons who lack capacity to consent from the opportunity to participate in research

The mere presence of a cognitive impairment should not lead to a presumption that a person is incapable of making a decision regarding participation in research and of giving valid informed consent. Yet sometimes these conditions impair the decision-making capacity required to give a valid informed consent, raising ethical concerns about the vulnerability of persons with cognitive impairments in research. Such concerns may have an impact on their research participation. In such cases, when specifically approved by the IRB in advance of implementation, use of surrogate consent may be an appropriate alternative to support the subject's participation in research.

The following guidance provides direction on obtaining from a surrogate decision maker the valid informed consent to participate in research for an adult subject who is cognitively impaired, lacks capacity, or suffers a serious or life-threatening disease.

Guidelines for IRB Approval of Surrogate Consent Use for Research

Surrogate consent for participation in a research study should be employed only to the extent that it is consistent with the intent of the Common Rule (45 CFR 46, Subpart A) and all other federal and state laws and regulations pertaining to protecting human subjects participating in research. AB 2328, codified as California Health & Safety Code Section 24178 and effective January 1, 2003, clarifies who may serve as a research subject's "legally authorized representative", referenced in 45 CFR 46 and therefore authorized under those federal regulations to provide surrogate consent for the potential research subject (hereafter referred to as the "subject") to participate in research.

While no specific set of criteria can encompass all conceivable situations in which the use of surrogate consent complies with the intent of the Common Rule, the following criteria should be viewed as fundamental guidelines to be used by the UC IRBs 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.
- Surrogate consent is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB.
- Surrogate consent is requested through the application process for new research studies or through the modification process for an existing protocol.
- As in all human subjects research, the IRB must consider carefully the risk/benefit ratio of the particular study for the targeted population.
- As with all mental health research conducted by the University, the confidentiality requirements of California Welfare & Institutions Code Section 5328(e) must be complied with.
- The IRB may consider whether the frequency of a specific protocol's review cycle should be reasonably modified when surrogate consent is implemented.
- The IRB application/modification form should detail the criteria under which surrogate consent may be sought.
- The investigator shall include in the IRB application/modification form a protocol-specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may require the consent of a legally authorized representative. If the investigator determines that the subject lacks decision-making capacity, the investigator shall, consistent with the standard consent process describe the research to the subject and the investigator's intent to obtain surrogate consent; and document this communication in the research file/chart, supplemented with a brief note in the subject's medical record, which references the research file and confirms that the research protocol was described to the subject. However, if the investigator determines that the subject is non-responsive, the investigator shall document that observation in the research file/chart, supplemented with a brief note in the subject's medical record, which references the research file.
- 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.

Determining the decision-making capacity of the subject:

- Whenever possible, investigators will attempt to obtain informed consent directly from the subject.
- The application reviewed by the IRB must detail a protocol-specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may qualify for surrogate consent. 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.

[Applebaum, PS and T. Grisso. "MacCAT-CR: MacArthur Competence Assessment Tool for Clinical Research. Professional Resource Press, 2001]

The capacity to understand all of these concepts may not be necessary in order to consent to participate in a particular research protocol -- greater capacity is required for higher-risk protocols. This standard should be used for determining the capacity of the surrogate as well, if necessary.

- In protocols in which a surrogate's consent has been approved by the IRB, 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.

Guidance for Investigators For the Use of Surrogate Consent

Investigators must apply to the IRB for use of surrogate consent that is specific to the particular study being reviewed. This request may be made through the protocol application process for new protocols or through the modification process for ongoing protocols. Upon approval by the IRB for use within a specific protocol, the investigator shall apply the use of surrogate consent on a case-by-case basis within that protocol.

Determining the decision-making capacity of the subject:

- Whenever possible, investigators will attempt to obtain informed consent directly from the subject.
- The application for IRB review must detail a protocol-specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may qualify for surrogate consent. While there are no standardized measures for determining capacity to consent, investigators may assess subject 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.

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The capacity to understand all of these concepts may not be necessary in order to consent to participate in a particular research protocol -- greater capacity is required for higher-risk protocols. This standard should be used for determining the capacity of the surrogate as well, if necessary.

- If the investigator determines that the subject lacks decision-making capacity, the investigator shall inform the subject of the investigator's intent to seek surrogate consent and shall document this discussion in the research file/chart. If the subject is unconscious due to trauma or due to medication administered to treat that trauma, the investigator shall document that condition in the research file/chart and the above described required discussion regarding intent to seek surrogate consent shall be waived. If the subject expresses resistance or dissent to participation or to the use of surrogate consent, the subject shall be excluded from the research study.

Investigators' Responsibilities Regarding Surrogate Decision-makers:

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 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.

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.

In both a non-emergency room and an emergency-room setting:

- 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. 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).
- 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.

- 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. NOTE: 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 psych unit because conservators and guardians were considered legally-authorized representatives.
- In protocols in which a surrogate's consent has been approved by the IRB, 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.

Re-consenting 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.

Guidance to Investigators Concerning the Surrogate's Self-Certification Form

- 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.
- 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.

