1 PURPOSE

1.1 This guidance establishes the process to obtain informed consent from the legally authorized representatives of adults unable to consent.

1.2 This guidance begins when the investigator or their designee determines that consent from the legally authorized representative of an adult unable to consent should be obtained.

1.3 This guidance ends when the investigator or designee has obtained the informed consent from the legally authorized representative of an adult unable to consent.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 DHHS and FDA regulations require that consent for research be obtained from the subject's legally authorized representative (LAR) See *GUIDANCE: Definitions (HRP-001)*, if the subject lacks the capacity to consent.

3.2 Section 24178 of the California Health and Safety Code addresses surrogate decision making by a legally authorized representative in most, but not all research situations.

3.2.1 Surrogate decision makers under Section 24178 may be used when:

3.2.1.1 The informed consent has not been waived by the IRB;

3.2.1.2 The individual is unable to consent and does not express dissent or resistance to participation;

3.2.1.3 The individual is not an inpatient on a psychiatric unit or in a mental health facility or a patient on a psychiatric hold; and

3.2.1.4 The research involves a medical experiment

3.3 The following surrogate decision makers under the following circumstances may give informed consent for the individual to participate in the research.

3.3.1 For nonemergency room environments, surrogate informed consent may be obtained from a surrogate decision maker with reasonable knowledge of the subject, who shall include any of the following persons in the following descending order of priority:

3.3.1.1 Agent pursuant to an advance health care directive

3.3.1.2 The conservator or guardian having the authority to make health care decisions for the person

3.3.1.3 The spouse

3.3.1.4 The domestic partner (as defined in Section 297 of the Family Code)

3.3.1.5 An adult son or daughter

3.3.1.6 A custodial parent

3.3.1.7 Any adult brother or sister

3.3.1.8 Any adult grandchild

3.3.1.9 An available adult relative with the closest degree of kinship to the person

3.3.1.10 When there are two or more available persons who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

3.3.1.11 When there are two or more available persons who are in different orders of priority, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.

3.3.2 For an emergency room environment, surrogate informed consent may be obtained from a surrogate decision maker who is any of the following persons:

3.3.2.1 Agent pursuant to an advance health care directive

3.3.2.2 The conservator or guardian having the authority to make health care decisions for the person

3.3.2.3 The spouse

3.3.2.4 The domestic partner (as defined in Section 297 of the Family Code)
3.3.2.5 An adult son or daughter
3.3.2.6 A custodial parent of the person
3.3.2.7 Any adult brother or sister
3.3.2.8 When there are two or more available persons, refusal to consent by one person shall not be superseded by any other of those persons.

4 RESPONSIBILITIES

4.1 Investigators are to follow this guidance when obtaining permission for adults unable to consent to take part in research.

5 PROCEDURE

5.1 Criteria for Use of Surrogate Consent: Consistent with California State Law, the SHC IRB uses the following criteria when determining whether to permit the use of surrogate consent for participation in a research study:

5.1.1 Surrogate consent may be permitted by the IRB in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research participants.

5.1.2 Investigators must include the following in the application for review by the IRB using *FORM: Initial IRB Review Application (HRP-211)*:

5.1.2.1 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.

5.1.2.2 Whether the participants may have a medical condition that may render them temporarily unable to provide informed consent and/or cognitive impairments such as mental retardation, dementia, or psychosis, see *CHECKLIST: Research Involving Cognitively Impaired Adults (HRP-417)*;

5.1.2.3 If the research participant lacks capacity to consent, the investigator will describe the research to the participant in a manner consistent with the standard consent process and indicate the intent to obtain surrogate consent. Note: This communication should be documented in the research record (source document). If, however, the research participant is non-responsive, the investigator will document this observation in the research record (source document) and a note in the participant's medical record that references the research record.

5.1.2.4 If the research participant expresses resistance or dissent to being in the research or to the use of the surrogate consent by word or gesture, s/he will be excluded from the research study.

5.2 Determining Capacity to Consent. Whenever possible, investigators should attempt to obtain informed consent directly from the research participant.

5.2.1 While 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:

5.2.1.1 Nature of the research and the information relevant to his/her participation;
5.2.1.2 Consequences of participation for their own situation, especially concerning their health condition; and
5.2.1.3 Consequences of the alternatives to participation.
5.2.1.4 Lack of capacity to consent should be documented in the medical record.

5.3 Consent is an ongoing process. All applicable criteria that would trigger re-consent of a research participant in any study also applies to participants whose consent have been provided by a surrogate. In addition:

5.3.1 A research participant who regains the cognitive ability to consent must be re-consented using the standard consenting procedure and offered the options listed below. These options should be included in the initial consent form:

5.3.1.1 Remain in the study
5.3.1.2 Withdraw from the study and allow use of collected data/specimens
5.3.1.3 Withdraw from the study, including withdrawal of collected data and specimens from further research use.

5.3.2 In the event a research participant 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.

5.3.3 In the event that the surrogate dies, the research participant must be re-consented subsequent to any event that would otherwise trigger re-consenting the participant.

6 MATERIALS

6.1 GUIDANCE: Definitions (HRP-001)
6.2 FORM: Initial IRB Review Application (HRP-211)
6.3 CHECKLIST: Research Involving Cognitively Impaired Adults (HRP-417)

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.116, 45 CFR §46.402
7.2 21 CFR §50.3
7.3 Section 24170-24178 California Health and Safety Code

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.