1 PURPOSE

1.1 This guidance establishes the process to obtain informed consent from the legally authorized representative (LAR) of adults who are unable to provide informed consent.

1.2 This guidance begins when the investigator or their designee determines that an adult is unable to provide informed consent, and that surrogate consent should be obtained from the subject's LAR.

1.3 This guidance ends when the investigator or designee has obtained informed consent from the subject's LAR.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENT

3.1 Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations require that informed consent for participation in research is obtained from the subject's legally authorized representative (LAR) if the subject lacks capacity to provide informed consent. See *GUIDANCE: Definitions (HRP-001)*.

3.2 Section 24178 in Chapter 1.3 of the California Health and Safety Code permits surrogate decision making by an LAR in most, but not all research situations.

3.2.1 Surrogate decision makers may be used when:

3.2.1.1 The informed consent has not been waived by the Institutional Review Board (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 research involves a medical experiment that relates to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research subjects.

3.2.2 Surrogate decision makers may not give consent:

3.2.1.4 For inpatients in an inpatient psychiatric ward or behavioral health facility.

3.2.1.5 For inpatients on a psychiatric hold.

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

3.3.1 Nonemergency room environments - If a person is unable to provide informed consent and does not express dissent or resistance to participation, 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 Emergency room environment - If a person is unable to provide informed consent and does not express dissent or resistance to participation, 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

3.4 This guidance and the requirements of *GUIDANCE: Research Involving Vulnerable Populations (HRP-053)* also apply when a research study involves populations with diminished or impaired decision-making capacity not covered by specific policies and procedures.

4 RESPONSIBILITIES

4.1 Investigators are to follow this guidance when obtaining permission for adults who are unable to provide informed consent for participation in research.

5 PROCEDURE

5.1 Criteria for Use of Surrogate Consent: Consistent with California State Law, the Sharp Health Care (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 impaired decision-making capacity or serious or life-threatening diseases and conditions of the research participants.

5.1.2 When investigators are likely to approach adults who lack capacity to provide informed consent, they 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 potential 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 if the subject has impaired decision-making capacity such as a developmental delay, dementia, or psychosis.

5.1.2.3 Investigators are encouraged to use *CHECKLIST: Research Involving Adults with Impaired Decision-Making Capacity (HRP-417)* to evaluate whether it is appropriate to include this population in the research. A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document. However, non-therapeutic clinical trials may be conducted in participants with consent of their LAR provided the following conditions are fulfilled:

- Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended.

- The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
- The foreseeable risks to the participants are low.
- The negative impact on the participant's well-being is minimized and low.
- The clinical trial is not prohibited by law.
- Participants in these trials should be particularly closely monitored.
- Participants should be withdrawn if they appear to be unduly distressed.
- The opinion of the SHC IRB is expressly sought on the inclusion of such participants via FORM: Initial IRB Review Application (HRP-211), and the investigator's / sponsor's written opinion (i.e., the protocol) covers this aspect.

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 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.

- This communication should be documented in the research record (source document). However, if 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.

5.2.1.5 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, they will be excluded from the research study.

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 If 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 GUIDANCE: Research Involving Vulnerable Populations (HRP-053)

6.3 FORM: Initial IRB Review Application (HRP-211)

6.4 CHECKLIST: Research Involving Adults with Impaired Decision-Making Capacity (HRP-417)

7 REFERENCES

7.1 FDA: 21 CFR 50.3

7.2 DHHS: 45 CFR 46.102; 45 CFR 46.116; 45 CFR 46.402

7.3 ICH-GCP (E6): 4.8.13; 4.8.14

7.4 California Health and Safety Code: Chapter 1.3 Section 24178

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