

Policy Number: 30

Title: Prospectively Obtained and Legally Effective Informed Consent

Date of Last Revision: 07/28/06, 09/13/10, 06/05/13, 05/11/15

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her legally authorized representative or surrogate decision maker.

- I. The IRB evaluates and assures that provisions are made to obtain legally effective informed consent prospectively from each research participant or permission from his/her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations (See IRB Policy 32).
- II. Documentation of informed consent is obtained unless alternate procedures are approved by the IRB (See IRB Policy 31). The IRB reviews all informed consent documents to assure the adequacy of the information contained in the consent document, and adherence to Federal regulations regarding the required elements of informed consent (See IRB Procedure 30.B).
- III. Informed consent is obtained from the participant or permission from a legally authorized representative prior to initiating research activities. This includes recruitment and screening procedures. The researcher will give either the participant or the representative adequate opportunity to read the consent form before it is signed. A copy of the consent document will be given to the person signing the consent document. Lead Researchers (LRs) that plan on enrolling research participants in other states or countries should take care to comply with local law in determining who qualifies as a legally authorized representative/surrogate decision maker.
 - A. Children - For subjects < 18 years of age, their parents or legal guardians are the legally authorized representatives who may grant permission for their participation in research.
 1. Parents - Only the parents may grant permission for their child's participation in research. Assent is to be sought from the child, only after permission has been obtained from the parents. Grandparents and other relatives or caregivers may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the Lead Researcher (LR) must obtain a copy of the court order as evidence of that person's authority to grant permission for participation in research on the child's behalf.
 2. Children in State Custody - According to the California Department of Children's Services' (DCS) applicable policies by virtue of the court order granting DCS legal custody of certain children (e.g., foster children) that Department is the agency that is authorized to grant permission for participation in research for children in their custody. The decision of whether to grant permission for research is made on a case-by-case basis by DCS. In such cases, the LR must obtain a copy of the court order from DCS.
 3. Mature Minors or Emancipated Minors - In certain limited circumstances, it may be appropriate to allow a mature minor to consent to participation in a research study in the absence of the permission of a parent or legal guardian if the minor has the sufficient capacity to consent to the procedures involved in the research study.
 - a. The IRB will determine whether the inclusion of mature minors or emancipated

minors in research activities in the absence of the permission of a parent or legal is appropriate. Further, each situation is judged on a case-by-case basis. For clinical investigations, UCIMC Hospital Administration should be consulted before initiating any research activity including screening. Documentation of those decisions must be included in the research file.

- b. The following information provides examples of circumstances under which California law combined with federal regulations permits individuals under 18 to enroll in research without permission from parent(s) or guardian(s):
 - (1) Minors may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not necessarily to sterilization or abortion [California Family Code Section 6925; Health and Safety Code Section 123450 for abortion].
 - (2) Minors 12 years of age or older have the legal right to consent on their own behalf, for:
 - (a) Mental health treatment or counseling on an outpatient basis or residential shelter services (in limited circumstances) [California Family Code Section 6924].
 - (b) Medical care related to the diagnosis or treatment of infectious, contagious or communicable diseases that are required to be reported to the local health officer or a related sexually transmitted disease [California Family Code Section 6926].
 - (c) Medical care related to the diagnosis or treatment of the condition and collection of medical evidence with regard to alleged rape or sexual assault [California Family Code Section 6927].
 - (d) Medical care and counseling related to the diagnosis and treatment of an alcohol or drug-related problem [California Family Code Section 6929].
 - (3) Self-sufficient minors who are:
 - (a) 15 years of age or older;
 - (b) living separately from their parents/guardians; and
 - (c) managing their own financial affairs have the legal right to consent on their own behalf to medical or dental care [California Family Code 6922].
 - (4) Emancipated minors, those who are:
 - (a) married or divorced
 - (b) on active duty in the U.S. armed forces *or* emancipated by the court; and
 - (c) have the legal right to consent on their own behalf to medical, dental, or mental health treatment. They also have extensive other rights to enter into legal and business arrangements, and so can consent to be included in other research (e.g., interviews, surveys) [California Family Code 7000-7143].
- c. Capacity to consent depends upon:
 - (1) The age, ability, experience, education, training, and degree of maturity and judgment of the minor. A minor between the ages of fourteen (14) and eighteen (18) may have such capacity, but a minor under the age of fourteen (14) would rarely have such capacity;
 - (2) The conduct and demeanor at the time consent is to be given;
 - (3) The totality of the circumstances;
 - (4) The nature of the proposed research procedures and their risks, probable consequences, benefits, and alternatives to the treatment; and

(5) The minor's ability to appreciate the nature, risks, consequences, benefits, and alternatives of the proposed research procedures.

- B. Cognitively Impaired Adult Participants - If a prospective adult subject lacks the capacity to consent, his or her legally authorized representative may grant permission, on their behalf, for their participation in research. See IRB Procedure 30.C for the hierarchy of individuals who qualify as surrogate decision makers. For example, the prospective adult subject's agent pursuant to an advance health care directive may grant surrogate consent to participate in research. Followed by the conservator or guardian of the person having the authority to make healthcare decisions for the person; and the spouse of the individual.
1. The Investigator must request approval from the IRB to obtain the consent of a surrogate decision-maker.
 2. Longitudinal Research Extended over Time - Studies involving subjects who are cognitively impaired may take place over extended periods of time. The IRB should consider whether and when periodic reconsenting of individuals is required to assure that a subject's continued involvement is voluntary. The IRB may require that the Investigator re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB may consider whether and when to reassess decision-making capacity.

IV. **Experimental Subject's Bill of Rights**

The State of California requires that all subjects enrolled in medical experimentation projects receive and sign a copy of the Experimental Subject's Bill of Rights.

V. **Clinicaltrials.gov**

As required by United States law, for projects that meet the definition of a clinical trial, the consent form will include a statement that a description of the clinical trial will be available on <http://www.clinicaltrials.gov>. The website will not include information that can identify the participant. At most, the website will include a summary of the results. The participant can reach the website at any time (See IRB Policy 57 for definition(s) of a clinical trial).

References:

45 CFR 46.109(b)

45 CFR 46.111

45 CFR 46.116 and 46.117

21 CFR 50.20

21 CFR 56.109(b)

21 CFR 56.111 (a)(4)

21 CFR 50.27(a)

21 CFR 56.111(a)(5)

21 CFR 50.24, 50.25 and 50.55

Information Sheet: A Guide to Informed Consent

OHRP Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained (OPRR REPORTS 95-03)

IRB Procedure Section 30.C – "Procedure for Determining Surrogate Decision-Maker for Research"

IRB Policies 36-40 - "Vulnerable Populations"

California Family Code - Sections 6922-6929

California Family Code - Sections 7000-7143

Health and Safety Code - Section 123450

Procedure Number: 30.A**Title: Procedure for Obtaining Prospective and Legally Effective Informed Consent****Procedure:**

This procedure outlines the responsibilities of the UC Irvine (UCI) Institutional Review Board (IRB) and the Investigator in obtaining legally effective and prospective informed consent from research participants or their legally-authorized representatives.

I. Lead Researcher (LR) Responsibilities

- A. The LR provides a detailed description of the intended method and process for obtaining informed consent in the initial IRB Application, applicable Appendices, and Protocol Narrative.
- B. All informed consent documents (full written consent documents, oral scripts, study information sheets, and assent forms) are submitted for review and approval by the UCI IRB prior to use.
- C. Any changes in the informed consent process or documents are submitted as a modification request to the IRB for review and approval prior to use.
- D. The informed consent process must:
 - 1. Be solicited in circumstances that minimize the possibility of coercion and undue influence;
 - 2. Utilize language understandable to the participant or their legally-authorized representative – recommended 6 – 8th grade reading level. (Investigators may use Readability Statistics tool available in the Spelling and Grammar checking function of Microsoft Word to validate readability and the Simplification Guide to Medical Terms on the HRPP website);
 - 3. Not waive or appear to waive participant's or representative's rights; and
 - 4. Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by Federal regulations (See IRB Procedure 30.B).
- E. Unless specifically waived by the IRB, informed consent is documented in writing through the use of a current IRB-approved informed consent document signed and dated by the participant or by the participant's legally authorized representative prior to enrollment or participation in any phase of the research study.
- F. The LR assures the informed consent process in research is an ongoing exchange of information between the research team and the study participants throughout the course of a research study. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document.

II. IRB Committee Responsibilities

- A. The IRB Committee, the Chairperson or his/her designee reviews the planned research activities to assure that the informed consent document is congruent with the IRB application, Investigator's brochure, Sponsor's or Investigator's protocol, grant and/or contract, and contains the necessary elements of informed consent as required by the applicable regulations.
- B. When reviewing the informed consent document, the Reviewers may request necessary revisions to the content, language, punctuation, and/or grammar in order for the intended target population to clearly understand the proposed research activities and make an informed decision on whether to participate in the research.

- C. The IRB Committee, the Chairperson or his/her designee ensures that research subjects are provided with the "Experimental Subjects' Bill of Rights" document during the IRB approved consent process to inform prospective research participants of their rights as research subjects.
- D. The IRB Committee, the Chairperson or his/her designee evaluates the circumstances of the informed consent process and method of documentation, indicating whether the process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study.
- E. The IRB Committee, the Chairperson or his/her designee evaluates whether the research involves participants who have diminished decision-making capacity, and if so, provides additional safeguards to ensure appropriate consent (See IRB Policies 33, 36, 38 and 39)
- F. When following a Department of Defense (DoD) Addendum, the IRB must determine that the disclosures included in the consent document includes that provisions for research-related injury follow the requirements of the DoD component.
- G. When following Department of Justice regulations and guidance, for research funded by the National Institute of Justice, the following applies:
 - 1. The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
 - 2. Under a privacy certificate, researchers and research staff does not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.
- H. For research conducted within the Bureau of Prisons, required elements of disclosure in the consent document include:
 - 1. Identification of the principal investigator(s);
 - 2. Anticipated uses of the results of the research;
 - 3. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable);
 - 4. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization and
 - 5. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

III. IRB Analyst or Higher Responsibilities

- A. The Analyst conducts a pre-review of the informed consent process and documents submitted with a new study application to determine that the correct forms have been utilized for the targeted population; assesses the readability of the document, and assures that all the necessary elements as required by the Federal regulations are present for adequate informed consent.
- B. If additional information regarding the informed consent process or documentation is needed, the Analyst contacts the LR and requests the additional information.

References:

45 CFR 46.111
 45 CFR 46.116 and 46.117
 21 CFR 50.24 and 50.25
 OHRP Guidance Document: Informed Consent Tips, March 1993

OHRP Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained (OPRR
REPORTS 95-03)
IRB Policies 36-40 "Vulnerable Populations"
DoD: DoDD 3216.2, para. 5.3.4; SECNAVINST 3900.39D, para. 6a(5)
28 CFR 512.16

Procedure Number: 30.B

Title: Procedure for Incorporating Elements of Informed Consent

Procedure:

This procedure outlines the responsibilities of the UC Irvine (UCI) Institutional Review Board (IRB) and the Investigator in incorporating the required elements into the informed consent document as required by the Federal regulations.

I. Lead Researcher (LR) Responsibilities

- A. Required Elements. The LR is responsible for incorporating the elements of informed consent as required by Federal Regulations into each informed consent document. The basic required elements of consent to be included in each informed consent document are:
1. A clear statement that the study involves “research”;
 2. An explanation of the purposes of the research;
 3. The expected duration of the subject’s participation;
 4. A complete description of the procedures to be followed, and identification of procedures that are performed as standard of care and identification of procedures that are performed solely for the purposes of research;
 5. A description of the reasonably foreseeable risks and discomforts;
 6. A description of any benefits to the participant or others that may reasonably be expected from the research;
 7. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
 8. A description of the extent to which confidentiality of records identifying the participant and privacy will be maintained;
 9. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained (See IRB Policy 26);
 10. An explanation of whom to contact for answers to pertinent questions about the research and to voice comment or concerns (e.g., Investigator or the IRB) and research participants’ rights (e.g., ORA), and whom to contact in the event of a research-related injury to the participant with an alternate number in case no answer is received; and
 11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- B. Additional Elements. The informed consent document should, where appropriate, include the following additional elements:
1. For women of child bearing potential, a statement that the particular treatment or procedure may involve risks to the participant (or the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
 2. Anticipated circumstances under which the subject’s participation may be terminated by the Investigator without regard to the participant’s consent;
 3. Any additional costs to the participant that may result from participation in the research;
 4. The consequences of a participant’s decision to withdraw from the research and

procedures for orderly termination of participation by the subject;

- a) When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. *The consent document cannot give the participant the option of having data removed.*
 - b) A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under these circumstances, the discussion with the participant would distinguish between study- related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
 - (1) The researcher must obtain the participant's informed consent for this limited participation in the study (assuming such a situation was not described in the original consent form). The IRB approves the consent document.
 - c) If a participant withdraws from the interventional part of the study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participants' withdrawal from the study, and may consult public records, such as those that establish survival status.
5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant;
- a) If there are significant new findings, the LR (with Committee input) should update the consent form to include this information and submit the re-consent cover letter to summarize the major changes. The re-consent cover letter template is available on the IRB Forms website.
 - (1) Examples of when re-consenting should be required:
 - (a) Increase in risk;
 - (b) New risks identified;
 - (c) Decrease in anticipated benefits; and
 - (d) Change in research procedures.
 - (2) The IRB will also consider other situations where re-consenting may be necessary (e.g., Change in Lead Researcher).
6. The approximate number of participants involved in the study;
7. Study treatment(s) and the probability of random assignment to placebo or to each treatment;
8. Additional information pertaining to the use of biological materials for research, especially genetic research;
9. A statement noting the possibility that the FDA may inspect the study records;
10. The type and amount of compensation, if any, the participant is to receive for study participation, and the schedule of compensation (i.e., whether it will be pro-rated).
11. Notification of any potential conflict of interest.
12. Any additional information that may be required by state law or institutional policy to obtain legally effective informed consent.
13. The IRB may require that information, in addition to that required in Federal

- regulations, be given to research participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of participants.
- C. No Omission of Required Elements unless a Waiver is granted. Required elements of informed consent may not be omitted unless waived by the IRB (See IRB Policy 32) In addition, there may not be discrepancies within the informed consent documents, the IRB application, the Sponsor's or Investigator's Protocol, the Investigator's Brochure, the grant and/or the contract regarding the purpose, risks, and benefits of the research. The IRB encourages Investigators to use the IRB template informed consent document when developing consent documents. Biomedical and Social/Behavioral templates are available on the IRB website at <http://www.research.uci.edu/ora/forms/> under the heading "IRB Consent Forms."
- D. Second Person. The language of the consent documents should be in the second person style (i.e., "you, your"), which may help convey that there is a choice to be made by the participant rather than a presumption of the participant's consent with the use of the first person style (i.e., "I, me, my").
- E. No Unproven Claims of Effectiveness. No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the informed consent documents.
- F. No Complex Language. The information provided in the informed consent documents must be in a language understandable to the participant (target population). The informed consent documents should not include complex language that would not be understandable to all participants. Technical and scientific terms should be adequately explained using common or lay terminology consistently. Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is preferred, it should be used consistently throughout the informed consent documents. Devices and procedures should also be described consistently throughout the documents and explained in simple language. It is generally recommended that the adult consent documents be written at a sixth to eighth-grade reading level.
- G. No Exculpatory Language. The informed consent documents may not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.
- H. FDA Regulated Test Articles. For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents should include a statement that a purpose of the study includes an evaluation of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety. In studies that also evaluate the effectiveness of the test article, informed consent documents should include that purpose, but should not contain claims of effectiveness.
1. Phase I Studies. Potential participants should be told, and a statement included in the purpose of the informed consent document, that Phase I studies are designed to determine safety, but not effectiveness. They are also designed to determine toxicity, and severe toxicity is a planned event for a subset of participants, and direct benefit is both not intended and extremely unlikely. In addition, the informed consent document should include an explicit statement that the dose administered is not chosen to maximize the chance of effect.
 2. Phase II and Phase III Studies. Potential participants should be told, and a statement included in the purpose of the informed consent document, that Phase II and III studies are designed to determine both safety and effectiveness.

II. IRB Committee Responsibilities

- A. The IRB Committee, the Chairperson or his/her designee will review the informed consent documents to assure the documents contain all the required elements of consent as defined by the Federal Regulations and determine the additional elements that are appropriate and should be incorporated into the documents.
- B. The IRB Committee, the Chairperson or his/her designee will complete the Informed Consent portion of the IRB Reviewer's Checklist.
- C. There are two circumstances under which the regulations give the IRB the authority to waive the required consent (See IRB Policy 32)
- D. The IRB Committee, the Chairperson or his/her designee will review the informed consent documents to assure:
 - 1. There are no discrepancies within the informed consent documents, the IRB application, the Sponsor's or Investigator's Protocol, or the Investigator's Brochure, regarding the purpose, risks, and benefits of the research;
 - 2. The language of the consent document is in the second person style (i.e., "you");
 - 3. The documents do not contain unproven claims of effectiveness or certainty of benefit, either implicit or explicit;
 - 4. The information provided in the informed consent documents is in a language understandable to the participant population and does not include complex language that would not be understandable to all participants;
 - 5. Informed consent documents do not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence;
 - 6. For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), the informed consent document(s) includes a statement that the purpose of the study includes:
 - a. For Phase I Studies: that the study is designed to determine safety, but not effectiveness. They are also designed to determine toxicity, and severe toxicity is a planned event for a subset of participants, and direct benefit is both not intended and extremely unlikely. In addition, the informed consent document should include an explicit statement that the dose administered is not chosen to maximize the chance of effect; and
 - b. For Phase II and Phase III Studies: that the purpose of the study is to determine both safety and effectiveness.

III. IRB Analyst or Higher Responsibilities

- A. The Analyst will conduct a pre-review of the informed consent documents submitted with a new study application to determine that the correct forms have been submitted for the targeted population, assess the readability of the document, and that all required elements are present for adequate informed consent, including if any additional elements are appropriate.
- B. If additional information regarding the informed consent process or documentation is needed, the Analyst will contact the LR and request the additional information.
- C. The Analyst will ensure that the IRB Chairperson or his/her reviewers completed the Informed Consent portion of the IRB Reviewer's Checklist.

Procedure Number 30.C

Title: Procedure for Determining Surrogate Decision-Maker for Research

Procedure:

This procedure outlines the responsibilities of the UC Irvine (UCI) Institutional Review Board (IRB) and the Lead Researcher (LR) in the approval and appropriate utilization of a Surrogate Decision-Maker in the context of research.

I. Specific Terminology Associated with Surrogate Decision-Maker

- A. Cognitively Impaired: Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
- B. Legally Authorized Representative (LAR): A person authorized either by statute or by court appointment to make legal decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- C. Surrogate Consent: If a prospective subject cannot consent on his/her own behalf, federal regulations permit researchers to obtain consent from a Surrogate Decision-Maker. Surrogate consent may be permitted by the IRB only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of the research subjects.

II. Lead Researcher (LR) Responsibilities

- A. IRB Approval
 1. New studies: The LR must indicate in the IRB application by completing Appendix E that the protocol will utilize consent of a Surrogate Decision-Maker and submit a consent document with the surrogate signature lines.
 2. Ongoing studies: If the LR later decides to utilize consent of a Surrogate Decision-Maker, a modification request must be submitted along with completion of Appendix E requesting the use of surrogate consent along with a revised informed consent document that incorporates the surrogate signature lines.
- B. Identifying the Surrogate Decision-Maker (SDM)
 1. The SDM identified to make health care decisions on the patient's behalf is generally the individual who should make decisions regarding the patient's participation in IRB-approved clinical research studies.
 2. California Health & Safety Code 24178 identifies the individuals who are legally authorized in California to provide surrogate consent for research.
 - a. For purposes of obtaining informed consent required for medical experiments in a *non-emergency room environment*, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a SDM with reasonable knowledge of the subject, who

shall include any of the following persons, in the following descending order of priority:

- (1) The person's agent pursuant to 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) An individual 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.
 - (10) When there are two or more available persons who, pursuant to "A" above, may give surrogate informed consent and 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.
 - (11) When there are two or more available persons who are in different orders of priority pursuant to "2a" above, 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.
- b. For purposes of obtaining informed consent required for medical experiments in an *emergency room environment*, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a SDM who is any of the following persons:
- (1) The person's agent pursuant to 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) An individual 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) When there are two or more available persons described in "2b" above, refusal to consent by one person shall not be superseded by any other of those persons.
 - (9) SDMs described in this section shall exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes, to the extent known to the SDM. Otherwise, the SDMs shall make the decision in accordance with the person's best interests. In determining the person's best interests, the SDM shall consider the person's personal values and his or her best estimation of what the person would have chosen if he or she were capable of making a decision.
- c. Any person who provides surrogate consent pursuant to subdivisions "2a" and "2b" above may not receive financial compensation for providing the consent.
- d. Section "2a" and "2b" above do not apply to any of the following persons, except as otherwise provided by law:
- (1) Persons who lack the capacity to give informed consent and who are involuntarily committed pursuant to Part 1 (commencing with Section 5000) of Division 5 of California Welfare and Institutions Code.

- (2) Persons who lack the capacity to give informed consent and who have been voluntarily admitted or have been admitted upon the request of a conservator pursuant to Chapter 1 (commencing with Section 6000) of Part 1 of Division 6 of the California Welfare and Institutions Code.
 - e. There are no additional state laws or federal laws providing additional protections to adults with cognitive impairments unable to provide informed consent for research participation.

- C. Required Documentation. In all cases involving adult patients who are incompetent or lacks decision-making capacity for healthcare decisions and consent of a Surrogate Decision-Maker is utilized, the LR, shall document in the medical record:
 - 1. The basis for their determination that the individual lacks decision-making capacity;
 - a. The investigator must detail a decision making capacity assessment which the IRB reviews and approves.
 - b. If the determination that the prospective participant lacks decision making capacity is based on a diagnosis of mental illness, the researcher obtains consultation with a psychiatrist or licensed psychologist.

 - 2. The identity of the SDM and the rationale for the selection of the individual as SDM, which shall be documented by the SDM on the "[Self-Certification of Surrogate Decision Makers for Participation in Research](#)" (PDF) form. A copy of the form should be provided to the SDM. In addition, the researcher must keep the original, signed form in the research records with the signed informed consent document.

- D. Obtaining Surrogate Consent
 - 1. Investigators must describe to potential SDMs 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 SDM is willing to undertake these ongoing responsibilities.
 - 2. Disclosures to be made to the participant must be made to the participant's legally authorized representative or SDM.
 - 3. Forcing or coercing participants to participate in a research study is prohibited.
 - 4. The SDM must complete the "*Self-Certification of Surrogate Decision Makers for Participation in Research*" form as an attachment to the informed consent document for the study, and be given a copy of this form along with a copy of the consent to keep.
 - 5. The Investigator 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 SDM, details the relationship of the surrogate to the participant 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).
 - 6. Potential SDMs 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.
 - 7. For non-emergency room environment research only: If the potential SDM 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 SDM.
 - 8. Surrogate decision-makers are prohibited from receiving any financial compensation

for providing consent. This does not prohibit the SDM from being reimbursed for expenses the SDM may incur related to their participation in the research.

9. Assessment of the decision-making capacity *of the SDM* should be implemented when the Investigator has reason to believe that the SDM's decision-making capacity may be impaired.

III. IRB Committee Responsibilities

- A. The IRB Committee, the Chairperson, or his/her designee will review the informed consent documents.
- B. The IRB Committee, the Chairperson or his/her designee will review the LR's rationale for the need to utilize consent by a Surrogate Decision-Maker assuring:
 1. There are appropriate safeguards in place for cognitively impaired participants;
 2. The LR has a thorough understanding of the appropriate use of consent of a Surrogate Decision-Maker in clinical research; and
 3. The LR has detailed how reconsenting will take place when and if an individual becomes competent to consent for oneself.
- C. The IRB should consider whether and when to require a reassessment of decision-making capacity. Additionally, after taking into account the study's anticipated length and the condition of the individuals to be included, whether and when periodic reconsenting of the SDM should be required to assure that a participant's continued involvement is voluntary.

IV. IRB Analyst or Higher Responsibilities

- A. The Analyst will conduct a pre-review of the informed consent document with the Surrogate Care Decision-Maker signature lines submitted with a new study application to determine that the correct forms have been submitted for the targeted population, assess the readability of the document, and verify all required elements are present for adequate informed consent, including if any additional elements are appropriate.
- B. If additional information regarding the informed consent process or documentation is needed, the Analyst will contact the LR and request the additional information.
- C. The Analyst will assure that the IRB database is updated appropriately to reflect IRB approval for the use of consent of a Surrogate Decision-Maker for the research.
- D. The Analyst will draft all approval letters. In addition, the Assistant will date stamp the informed consent document in accordance with IRB Policy 34.