

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, 09/16/22

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. General Requirements for Informed Consent Process

- A. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- B. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- C. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- D. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
 1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
 2. Informed consent must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- E. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- F. The IRB evaluates and assures that provisions are made to obtain legally effective informed consent prospectively from each research participant or permission from their legally authorized representative. There are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations. (See IRB Policy # 32.)

- G. 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.)
- H. The consent process 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. Alternatively, this form may be read to the subject or the subject's legally authorized representative.
- I. Unless documentation is waived by the IRB, informed consent shall be:
 - 1. Documented using a written informed consent form approved by the IRB and signed (either on paper or electronically) by the participant or the participant's legally authorized representative prior to initiating research activities. A written copy of the consent document will be given to the person signing the consent document. Per UCI Health IT, FDA-Regulated Studies must use DocuSign Part 11 for obtaining electronic signatures on the Informed Consent Form.
 - 2. Alternatively, a short form written informed consent form stating that the elements of informed consent required by [§46.116](#) have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by [§46.116\(a\)\(5\)\(i\)](#) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.
- J. 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. (See Policy # 29.)
- K. 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.
- L. 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. (See Policy # 57 for definition(s) of medical experimentation). (See *"General Information Often Requested by Study Sponsors"* for reason why UCI does not have signature lines on the Bill of Rights.)

- M. 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 Policy # 57 for definition(s) of a clinical trial.)
- N. For each clinical trial conducted / supported by HHS initially approved, or has transitioned to comply with the revised 2018 common rule requirements prior to enrollment closure on or after January 21, 2019, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.
 - 1. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
 - 2. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

II. Requirements for Informed Consent- Basic Elements

- A. The basic required elements of consent to be included in each informed consent document are as per the 2018 Common Rule and include:
 - 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
 - 2. A description of any reasonably foreseeable risks or discomforts to the subject;
 - 3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
 - 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - 6. 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;
 - 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject (See Policy # 26);
 - 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

III. Requirements for Informed Consent- Additional Elements

- A. One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:
 1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
 3. Any additional costs to the subject that may result from participation in the research;
 4. The consequences of a subject'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 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 and address the maintenance of privacy and confidentiality of the participant's information.
 - c) 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 prospectively.
 - d) 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 research that may relate to the subject's willingness to continue participation will be provided to the subject;
 - 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.
 - b) Examples of when re-consenting should be required:
 - c) Increase in risk;
 - d) New risks identified;
 - e) Decrease in anticipated benefits; and
 - f) Change in research procedures.
 - g) The IRB will also consider other situations where re-consenting may be necessary (e.g., Change in LR).
 6. The approximate number of subjects involved in the study;
 7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
 8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
 9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
 10. Study treatment(s) and the probability of random assignment to placebo or to each treatment;
 11. A statement noting the possibility that the FDA may inspect the study records;
 12. 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).
 13. Notification of any potential conflict of interest.
 14. Any additional information that may be required by state law or institutional policy to obtain legally effective informed consent.
 15. 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.
- B. UCI has elected to not implement the 2018 Common Rule elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

IV. Requirements for Informed Consent - Additional Consent Language Requirements

- A. 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 <https://research.uci.edu/human-research-protections/irb-forms/> under the heading "IRB Consent Forms."
- B. 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").
- C. 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.
- D. 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.
- E. 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.
- F. 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.
- G. 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.

- H. 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.

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

2018 Common Rule Changes to 45 CFR 46

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

This procedure outlines the responsibilities of the 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.
- 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 an Amendment 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;
 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 their 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 their 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 their 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 their 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 those 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. As applicable to the level of review, and considering the IRB review timeframe, the Analyst conducts a pre-review of the informed consent process and documents submitted with an IRB 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, including if any additional elements are appropriate.

- 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 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 of Informed Consent:** The LR is responsible for incorporating the basic and additional elements of informed consent as required by Federal Regulations and as applicable to the context of the study into each informed consent document.

II. IRB Committee Responsibilities

- A. The IRB Committee, the Chairperson or their 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 will ensure there are no discrepancies within the informed consent documents by utilizing the "Informed Consent Checklist" ensure the basic and additional elements of informed consent are incorporated, the IRB application, the Sponsor's or Investigator's Protocol, or the Investigator's Brochure, regarding the purpose, risks, and benefits of the research.

III. IRB Analyst or Higher Responsibilities

- A. As applicable to the level of review, and considering the IRB review timeframe, the Analyst conducts a pre-review of the informed consent process and documents submitted with an IRB 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, 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.

Procedure Number 30.C**Title: Procedure for Determining Surrogate Decision-Maker for Research****Procedure:**

This procedure outlines the responsibilities of the 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 their 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. Surrogate Consent in Non-Medical Research

- A. California law addresses surrogate consent in the context of medical research. The Office of the President has acknowledged that campuses may permit the same surrogates authorized by Section 24178 may also be considered in the context of non-medical research. Per the Common Rule, for research that is no more than minimal risk, the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances, and in such cases the need for surrogate consent may also be waived.

III. Lead Researcher (LR) Responsibilities

- A. IRB Approval
 - 1. New studies: The LR must indicate in the IRB Application 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, an Amendment request must be submitted requesting the use of surrogate consent along with a revised informed consent document that incorporates the surrogate signature lines.

- B. Assessing Capacity: Participants should be assessed on their abilities to understand and to express a reasoned choice concerning the following:
1. Nature of the research and the information relevant to their participation;
 2. Consequences of participation for their own situation, especially concerning their health condition; and
 3. Consequences of the alternatives to participation.
- Investigators may use the Decision-Making Capacity Assessment Tool to assess the understanding of the consent process of persons who may have cognitive impairments or may elicit the information using clinical interview procedures. The IRB may permit less formal procedures to assess capacity (e.g., assessment of capacity through routine **interactions with** the participant) when the study is no more than minimal risk.
- C. 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 agent named in the potential research participant's advance health care directive. The conservator or guardian of the potential research participant, with authority to make healthcare decisions for the potential participant.
 - (2) The spouse of the potential research participant.
 - (3) The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.
 - (4) An adult child of the potential research participant.
 - (5) A custodial parent of the potential research participant.
 - (6) An adult sibling of the potential research participant.
 - (7) An adult grandchild of the potential research participant.
 - (8) An available adult relative with the closest degree of kinship to the potential research participant, whose relationship to the potential participant does not fall within one of the above listed categories (e.g., aunt; uncle; cousin; etc.).
 - b. The investigator is responsible for making a reasonable effort to determine if that individual is available to serve as surrogate. 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. When there are two or more available persons who may provide surrogate consent and who are in the same order of priority (e.g., an adult son and daughter of the potential participant), if any of those persons in the same

order of priority expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

- c. 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 agent named in the potential research participant's advance health care directive.
 - (2) The conservator or guardian of the potential research participant, with authority to make health care decisions for the potential participant.
 - (3) The spouse of the potential research participant.
 - (4) The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.
 - (5) The adult child of the potential research participant.
 - (6) A custodial parent of the potential research participant.
 - (7) An adult sibling of the potential research participant.
 - (8) In emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.
 - (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 per Cal. Health & Safety Code § 24178(g).
- d. A surrogate decision-maker is prohibited from receiving financial compensation for providing consent per Cal. Health & Safety Code § 24178(i).
- e. Section "2a" and "2c" 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 the California Welfare and Institutions Code § 5000 *et seq*; or
 - (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.

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.
- c. The identity of the SDM and the rationale for the selection of the individual as SDM, which shall be documented on the [Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research](#) 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 Investigator must complete the Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California 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 Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research form verifies the criteria for the use of a surrogate decision maker and the category of the potential surrogate.
- 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 their designee will review the informed consent documents.
- B. The IRB Committee, the Chairperson or their 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. As applicable to the level of review, and considering the IRB review timeframe, the Analyst conducts a pre-review of the informed consent process and documents submitted with an IRB 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, 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 and stamp the informed consent document. (See Policy # 34.)

References:

University of California Guidance Memo 21-01: Surrogate Consent for Research – Updated Guidance, Dated 02/16/202.