

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 3.7  
Protected Populations

***Policy***

In studies where subjects likely to be vulnerable to coercion or undue influence are likely to participate, appropriate additional safeguards must be included in the study to protect their rights and welfare. In such cases, the investigator must provide sufficient justification for inclusion of vulnerable populations and a plan for how the rights of these subjects will be protected from possible coercion. The IRB must determine whether the involvement of such populations in research is justified and determine whether the proposed study minimizes or eliminates the risks to vulnerable subjects.

In making such determinations the IRB will consider the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits (e.g., the likelihood of benefit to the subject). The IRB will also determine whether relevant risks and benefits are thoroughly presented in documents and procedures used in the informed consent process. Issues that should be addressed by the IRB include whether:

1. Any monetary payments to subjects are not so great as to constitute an undue inducement;
2. The proposed safeguards are adequate to protect the rights and welfare of the subjects;
3. Minorities receive an equal share of the benefits of research and do not bear a disproportionate burden;
4. The possibility of exploitation can be reduced or eliminated.

Policy and procedure for prisoners, students and employees is provided here. Because of the complexity of the issues, specific policy guidance is provided in separate sections of this Policy and Procedures document for the following vulnerable populations: a) pregnant women and fetuses, b) children and c) research participants with impaired decision making capacity, and those likely to need surrogate consent.

***3.7.1 Projects Involving Prisoners***

If an investigator indicates on the Initial Application Form that prisoners may participate in the research, the following additional requirements will apply to IRB review of the project.

The IRB reviewing human research involving prisoners must meet the following specific requirements:

1. At least one member of the IRB will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a

particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

2. A majority of the IRB (exclusive of prisoner members) will have no association with the prison(s) involved, apart from their membership on the IRB.
3. The research goals of the project include one or more of the following:
  - a. Study of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - c. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the IRB has consulted with appropriate experts including experts in penology, medicine and ethics, and published notice in the Federal Register, of his intent to approve such research; or
  - d. Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well being of the subject. In cases where those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups, which may not benefit from the research, the study may proceed only after the UCSD HRPP has consulted with appropriate experts, including experts in penology, medicine and ethics, and published notice in the Federal Register, of his intent to approve such research
4. Any possible advantages accruing to the prisoner through participation the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.
5. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.
6. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
7. Any information given to subjects is presented in language that is appropriate for the subject population.
8. Adequate assurance exists that parole board(s) will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the human subjects research will have no effect on his/her parole;
9. Where there is need for follow-up examination or care of participants after the end of their participation in the research, adequate provision has been made for such

examination or care, taking into account the varying lengths of prisoner sentences, and for informing participants of this fact.;

In addition to meeting Federal regulations, the project must comply with all state and local requirements for inclusion of prisoners as subjects. The IRB strongly encourages the Principal Investigator to contact HHS about applying for HHS approval for inclusion of prisoners or wards of the court in research.

These policies also apply to subjects enrolled in a study who become incarcerated during the course of the study and remain incarcerated at the time that study-related procedures or treatment are to be performed. In order for study procedures to be performed while the subject is incarcerated, the study and its review must have met all of the requirements above. Incarceration will thus usually result in suspension or discontinuation from the study, depending on the circumstances of protocol and the duration of the incarceration. Subjects discontinued from a study due to incarceration must be withdrawn in an orderly manner that assures their safety. Their participation in the study may resume after release if the protocol allows.

Studies involving a subject population with a high probability of becoming incarcerated during the study (e.g., violent felons) may also be required to meet these requirements. The IRB will review such studies on a case-by-case basis. If the IRB determines that prisoner requirements will be applied, then the project and review process must meet the above criteria or be disapproved.

### ***Procedures***

1. The IRB Chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations.
2. The IRB Administrator will review the application to ascertain if vulnerable populations are likely to be recruited; secure a voting member who is a prisoner/prisoner advocate; and secure additional consultations to provide additional expertise on special populations.

### ***Applicable Regulations***

[45 CFR 46 Subpart C](#)

[OHRP Guidance on the Involvement of Prisoners](#)

[OHRP Prisoner Frequently Asked Questions](#)

[California Penal Code, Sections 3500-3524](#)

### ***3.7.2 Projects Involving Students and Employees***

Students (undergraduate, graduate, and medical students), and employees of UCSD, VASDHS, and SDCHS (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff, etc.) are considered vulnerable to undue influence. Such individuals may feel some pressure to participate in a researcher's study, especially if the requesting researcher is their supervisor, instructor, or someone who might be in a position to influence their future. Investigators must exercise great caution to avoid even the appearance of pressuring such individuals into enrollment or continued participation. When a UCSD research investigator wishes to include such individuals as human subjects, he or she must indicate so on the initial application or request a modification to an approved protocol.

In general, the IRB does not permit recruitment of employees from the investigator's own lab, department, or office, as a matter of local policy. However, for minimal risk studies the IRB will consider requests for waivers of this policy on a case-by-case basis. Students from an investigator's own lab or class may not be actively recruited into their research studies, but such students may freely volunteer to participate, to the same extent as anyone is free to respond to general recruitment advertisements.

When students participate in research studies for class credit they should be provided alternative methods of getting that credit that do not include participating in an experiment, and it is the investigator's responsibility to determine that those alternative methods exist. Wherever possible, student should be provided with a choice of research opportunities, including some not under the investigator. The IRB may require the informed consent form to state whether alternatives are available and what those alternatives are. The investigator must provide assurance that a student's experimental results, performance, or any confidential data will not be given to whomever is grading the student, except for stating whether the student participated or not unless the approved study design provides for this. Recruitment advertisements need to be approved by the IRB according to previously stated policy. Hospital volunteers are free to participate in research studies, but volunteers working in the investigators own area or lab should be afforded similar protections as described above for students.

#### ***Procedures***

1. The IRB Chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations.
2. The IRB Administrator will review the application to ascertain if vulnerable populations are likely to be recruited and secure additional consultations to provide additional expertise on special populations.

### ***3.7.3 Projects Involving Pregnant Women***

Pregnant women and fetuses are considered protected populations, and research must provide the additional protections listed here.

With regard to research involving the participation of pregnant women as research subjects, the following requirements must be met:

1. Appropriate studies on animals and non-pregnant individuals have been completed;
2. The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or the risk to the fetus is minimal.
3. Individuals engaged in the activity will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy or determining the viability of the fetus at the termination of the pregnancy.
4. No procedural changes that may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the research activity.
5. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of research activity.
6. Research activity as described may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if the purpose of the activity is to meet the health needs of the mother, his identity or whereabouts cannot reasonably be ascertained, he is not reasonably available, or the pregnancy resulted from rape.
7. The IRB will determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made to monitor the actual informed consent process such use of consent observers, audits, and/or site visits.

### ***Procedures***

1. The IRB Chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations.
2. The IRB Administrator will review the application to ascertain if vulnerable populations are likely to be recruited and secure additional consultations to provide additional expertise on special populations.

### ***Applicable Regulations***

[45 CFR 46 Subpart B](#)

[The NIH Revitalization Act of 1993 \(Public Law 103-43\)](#)

[Section 498B of the Public Health Service Act \(42 U.S.C. 298g-2\)](#)

### ***3.7.4 Projects Involving Fetuses or Fetal Tissue***

The University of California is compliant with California state law that permits research using human embryonic stem cells if that research is reviewed and approved by a federally registered IRB.

Research conducted by UCSD investigators that is funded by federal agencies must comply with provisions of the NIH Revitalization Act of 1993 (Public Law 103-43) with respect to use of fetal tissue.

The provisions of that act include the following:

1. *Human fetal tissue* means tissue or cells obtained from a dead embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.
2. Human fetal tissue may be used regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.
3. The woman donating the human fetal tissue must sign a statement declaring that the tissue is being donated for therapeutic transplantation research, the donation is being made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue, and the donation is being made without her (the donor) having been informed of the identity of those individuals who may be the recipients.
4. The attending physician must sign a statement declaring that the tissue has been obtained in accord with the donor's signed statement and that full disclosure has been made to the donating woman of: (1) The attending physician's interest, if any, in the research to be conducted with the tissue, and (2) any known medical risks to the donor or risks to her privacy that might be associated with the donation of the tissue and are in addition to the risks associated with the woman's medical care. In the case of tissue obtained pursuant to an induced abortion, the attending physician's statement must also declare that the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for donation, the abortion was conducted in accordance with applicable state law, and no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue.
5. The individual with the principal responsibility for conducting the research must sign a statement declaring that the individual is aware that the tissue is human fetal tissue donated for research purposes and may have been obtained pursuant to spontaneous or induced abortion or pursuant to a stillbirth; that the principally responsible researcher has provided such information to other individuals with responsibilities regarding the research; that the principally responsible researcher will require, prior to obtaining the consent of a person to be the recipient of a transplantation of the tissue, written acknowledgement of receipt of the foregoing information by such recipient; and that the principally responsible researcher has had no part in any decisions as to the timing, method, or procedure used to terminate the pregnancy made solely for the purposes of the research.
6. Research involving the transplantation of human fetal tissue for therapeutic purposes must be conducted in accord with applicable State law and the Secretary may not provide support for such research unless the applicant for assistance agrees to conduct the research. The conduct of such research by the Secretary must be in accord with applicable state and local law.

The provisions of section 498B of the Public Health Service Act (42 U.S.C. 298g-2), added by Public Law 1-3-43, the NIH Revitalization Act of 1993 are summarized as follows:

1. It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce. (Valuable consideration does not include reasonable payment associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.)
2. It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purposes of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be obtained pursuant to an induced abortion, and: (1) The donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual; (2) the donated tissue will be transplanted into a relative of the donating individual; or (3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion. (Valuable consideration does not include reasonable payments associated with the transplantation, processing, preservation, quality control or storage of human fetal tissue.)

The IRB, in reviewing research involving fetal tissue that is sponsored by federal agencies, will ensure that all requirements outlined in this section of the guidelines be met. Copies of all the required signed consent documents must be included with the application.

#### ***Procedures***

1. The IRB Chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations and fetal tissue.
2. The IRB Administrator will review the application to ascertain if vulnerable populations are likely to be recruited and secure additional consultations to provide additional expertise on special populations.

#### ***Applicable Regulations***

[45 CFR 46 Subpart B](#)

[The NIH Revitalization Act of 1993 \(Public Law 103-43\)](#)

[OHRP Guidance Fetal Tissue Transplantation](#)

[Section 498B of the Public Health Service Act \(42 U.S.C. 298g-2\)](#)

#### ***3.7.5 Projects Involving Children and Adolescents***

Research involving children as subjects must be reviewed by a full Committee regardless of the risks involved, and the committee must have appropriate membership to represent children's interests and pediatric expertise. The IRB will determine whether proposed research participants meet the federal and state definitions of "child," "emancipated" or "self-sufficient" minor, and are permitted by California law to consent to research. The Principal Investigator is responsible for determining whether specific individuals involved in research (minors and guardians) are qualified to provide permission or assent. The IRB

reviewing the study has additional responsibilities, to ensure that the study meets all requirements in 45 CFR 46. Subpart D “Additional DHHS Protections for Children Involved as Subjects in Research.”

Approval letters for research involving children will cite the specific provisions of Subpart D (sections 404-407) under which the approval is given. In addition, the IRB will document the conditions of parental and child or adolescent assent. In general, permission should be obtained from both parents before a child is enrolled in research. However, the IRB may find that the permission of one parent is sufficient for research to be conducted under [46.404](#) (minimal risk) or [46.405](#) (greater than minimal risk, direct benefit). When research is to be conducted under [46.406](#) and [46.407](#) permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The IRB will evaluate and document the conditions of parental and child or adolescent assent. This information will be reflected in correspondence to the investigators and in the IRB minutes.

### Definitions

For purposes of this policy the following definitions are used, consistent with federal (45 CFR 46 subpart D) and state regulations:

1. "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
2. "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
3. "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.
4. "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In California, a guardian may be a biological or adoptive parent or a legally appointed guardian. For wards of the court, usually an order from the judge is required in addition to permission from the person charged with care of the child.
5. "Minors" are people under 18 years of age. In California, minors generally may not consent to medical care or treatment, or research involving medical care or treatment, without a parent or legal guardian's permission. However, federal regulations interpreted with California legal exceptions, may permit minors in the following categories to consent to research:
  - a) "Emancipated Minor" is a person under age 18 who has been legally married, on active duty in the U.S, Armed forces, or emancipated by court order (California Family Code 7002).
  - b) "Self-Sufficient minor" is a person between age 15 and 18 living apart from parent or guardian, managing his or her own financial affairs, and not dependent on parents or guardian for medical care. (California Family Code 6922)

- c) Minors, 12 years or older, seeking care for certain condition or diseases (see California Family Code 6924-6929)

### ***Procedures***

1. The IRB Chair and IRB members will review the benefits of participation to ensure there are no coercive elements; ensure that the protocol and consent provide adequate protections for vulnerable populations; and verify that the research is in compliance with federal and institutional directives regarding vulnerable populations.
2. The IRB Administrator will review the application to ascertain if vulnerable populations are likely to be recruited and secure additional consultations to provide additional expertise on special populations.

### ***Applicable Regulations***

[45 CFR 46 Subpart D](#)

[OHRP Special Protections for Children as Research Subjects](#)

[OHRP Research Involving Children Frequently Asked Questions](#)

### ***3.7.6 Projects Involving Surrogate Consent and Populations with Impaired Decisional Capacity***

No person who has the capacity for consent may be enrolled in a study without his or her informed consent.

IRB review of projects involving surrogate consent (as evidenced by a “legally authorized representative” signature line in the consent document) shall conform to the requirements of California law AB2328 and Section 24178 of the California Health and Safety Code that specifies the requirements for and procedures related to the surrogate consent process.

Surrogate decision makers may be used when all of the following are true according to Section 24178 of the California Health and Safety Code:

1. Informed consent has not been waived by the IRB
2. The individual is unable to consent and does not express dissent or resistance to participation
3. The individual is not an inpatient on a psychiatric unit or in a mental health facility or a patient on a psychiatric hold
4. The research involves medical experimentation (not treatment)
5. The medical experiments relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and condition of research participants.

Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

The decisional capacity of a potential research subject should be evaluated when there are reasons to believe that the subject may not be capable of making voluntary and informed decisions about research participation. A Decisional Capacity Taskforce, convened in 2001 by the UCSD Department of Psychiatry at the request of the UCSD HRPP, issued investigator guidelines on this topic that are available on the UCSD IRB website.

For research protocols that involve subjects with mental disorders that may affect decision-making capacity, the IRB may determine that capacity assessments are necessary, unless the investigator can justify why such assessments would be unnecessary for a particular group. The requirement for an independent evaluator becomes increasingly justified as the risks to subjects increase.

For research that poses greater than minimal risk, the IRB should generally require investigators to use an appropriate means of determining the potential participant's capacity to consent. The Decisional Capacity Taskforce guidelines present several alternative approaches for meeting this requirement. Even in research involving only minimal risk, the IRB may still require that the study include a capacity assessment if there are reasons to believe that potential subjects' capacity may be impaired. It is not necessary to require a formal capacity assessment by an independent professional for all potential research subjects with mental disorders.

For research protocols involving subjects who have fluctuating or limited decision-making capacity the IRB should ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic re-consent should be considered in some cases. Third party consent monitors may be used during the recruitment and consenting process, or waiting periods may be required to allow more time for the subject to consider the information that has been presented.

It is often possible for investigators and others to enable persons with some decisional impairments to make voluntary and informed decisions to consent or refuse participation in research. Potential measures include repetitive teaching, group sessions, audiovisual presentations, and oral or written recall tests. Other measure might include follow-up questions to assess subject understanding, videotaping or audio-taping of consent interviews, second opinions, use of independent consent observers, or involvement and/or concurrent consent of a trusted family member or friend in the disclosure and decision-making process. In the event that a protocol may enroll subjects with diminished capacity to consent, the protocol should identify a plan for seeking the subject's assent. The IRB should evaluate whether assent of the participants is a requirement, and if so, whether the plan for assent is adequate. Mere failure to object should not, absent affirmative agreement, be construed as assent. Under no circumstances may a subject be forced or coerced to participate in a research study.

#### Determination of decisional capacity

Decisional capacity in the research context has been interpreted by the American Psychiatric Association as requiring the ability to:

1. evidence a choice;

2. understand relevant information;
3. appreciate the situation and its likely consequences; and
4. manipulate information rationally.

A range of professionals and methods may be utilized to assess capacity. In general the consent assessor should be a researcher or consultant familiar with dementias and qualified to assess and monitor capacity and consent in such subjects on an ongoing basis. The IRB will consider the qualifications of the proposed individual(s) and whether he or she is sufficiently independent of the research team and/or institution.

The protocol should describe who will conduct the assessment, the method by which prospective subjects' decisional capacity will be evaluated, and the criteria for identifying incapable subjects. Less formal procedures to assess potential subjects' capacity may be permitted if a formal assessment is not feasible. An example of a formal procedure could be a 5 to 10-item questionnaire read by the person administering the consent to the prospective subject that includes questions about key elements of the research (e.g. Name two study procedures. What do you do if you no longer want to be in the study? What alternatives are there to participating). Prospective subjects having adequate decisional capacity to provide informed consent must answer these questions correctly. Less formal procedures could include the ways professionals often make judgments about capacity in routine interactions.

#### Surrogate Consent

California law AB2328, codified as California Health & Safety Code Section 24178 became effective January 1, 2003 and clarifies who may serve as a research subject's "legally authorized representative." The IRB review of a new or revised application that proposes to have the option of consent by surrogates will address the project's compliance with the provisions of state law as noted below.

Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research subject. The investigator shall include in the IRB application/modification form a protocol-specific plan for the sequence of steps that will be employed to acquire and document surrogate consent provided by a legally authorized representative. These steps include the following:

1. Whenever possible, investigators will attempt to obtain informed consent directly from the subject.
2. If the potential research subject is obtunded, unconscious or otherwise obviously lacking in decision-making capacity, the investigator shall:
  - a) Document that observation in the research record and in the subject's medical record;
  - b) Proceed with the steps listed below under *Identifying Persons to Provide Surrogate Consent*
3. If the potential research subject has questionable capacity to consent but is not unresponsive, the investigator shall:

- a) Consistent with the standard consent process, describe the research to the subject;
- b) Perform and document an assessment of the participant's decisional-capacity relevant to the information provided about the research study;
- c) If lack of decisional capacity is evident, the investigator shall inform the potential research subject of the investigator's intent to obtain surrogate consent;
- d) If the subject expresses resistance or dissent to participation or to the use of surrogate consent by word or gesture, the subject shall be excluded from the research study.
- e) If no resistance or dissent is expressed by the potential research subject, the investigator shall document this fact, and document that the description of the research project was communicated to the subject by placing a note in the medical record and in the research record.
- f) Proceed with the steps listed below under *Identifying and Informing Persons providing Surrogate Consent*

#### Identifying Persons to Provide Surrogate Consent

##### In a non-emergency room environment

Surrogate consent may be obtained from any of the following potential surrogates who has reasonable knowledge of the subject, in the following descending order of priority:

1. The person's agent designated by an advance health care directive.
2. The conservator or guardian of the person having the authority to make health care decisions for the person.
3. The spouse of the person.
4. The domestic partner of the person as defined in Section 297 of the Family Code
5. An adult son or daughter of the person.
6. A custodial parent of the person.
7. Any adult brother or sister of the person.
8. Any adult grandchild of the person.
9. An available adult relative with the closest degree of kinship to the person.

In non-emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among the members of the highest available priority class of surrogates, (e.g., where two members of persons in the highest of categories (5) – (7) disagree and there is no person in categories (1) – (4) available.

In non-emergency room research settings only, the investigator is responsible for ensuring that the surrogate:

1. Has reasonable knowledge of the subject;
2. Is familiar with the subject's degree of impairment;
3. Is willing to serve as the substitute decision-maker;
4. Understands the risks, potential benefits, procedures and available alternatives to research participation;

5. Makes their decisions based on the subject's known preferences, and where the subject's preferences are unknown, makes decisions based upon the surrogate's judgment of what the subject's preferences would be if different from their own.

#### In an emergency room setting

The order of priority does not apply, nor does the surrogate have to show reasonable knowledge of the subject. Surrogate consent may be obtained from a surrogate decision maker who is any of the following:

1. The person's agent designated by an advance health care directive.
2. The conservator or guardian of the person having the authority to make health care decisions for the person.
3. The spouse of the person.
4. The domestic partner of the person as defined in Section 297 of the Family Code.
5. An adult son or daughter of the person.
6. A custodial parent of the person.
7. Any adult brother or sister of the person.

In emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.

#### Obtaining Consent from the Surrogate

1. Investigators shall describe to potential surrogates the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures, changes to the study, etc., in order to ensure that the surrogate will be willing to undertake these on-going responsibilities.
2. The surrogate shall complete the "Self-Certification of Surrogate Decision Makers for Participation in Research" form as an attachment to the informed consent document for the research study, and be given a copy of this form along with a copy of the consent to keep. In addition, the researcher 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 surrogate, details the relationship of the surrogate to the subject and the surrogate's qualifications demonstrating "reasonable knowledge" of the research subject. (Note: Section 3 of the "Self-Certification of Surrogate Decision Makers for Participation in Research" form is required only for surrogate consent in non-emergency room environment settings).
3. 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.
4. For non-emergency room environment research only, if the potential surrogate identifies a person of a higher degree of surrogacy, the investigator is responsible to contact such individuals to determine if they want to serve as surrogate.
5. Surrogates are prohibited from receiving any financial compensation for providing consent. This does not prohibit the surrogate from being reimbursed for

expenses the surrogate may incur related to the surrogate's participation in the research.

6. Assessment of the decision-making capacity *of the surrogate* should be implemented only when the investigator has reason to believe that the surrogate's decision-making capacity may be impaired.

NOTE: Surrogate consent to participate in research under California Health & Safety Code section 24178 **is not permitted** for persons in a State of California mental health facility inpatient psychiatric ward, or persons on psychiatric hold. This is more restrictive than the standard under previously existing law whereby an incapacitated adult with a conservator or guardian could be enrolled onto a study being conducted in an inpatient psychiatric unit because conservators and guardians were considered legally-authorized representatives.

#### Re-consenting of Research Subjects

Consenting is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study shall apply to subjects whose consent has been provided by a surrogate. In addition:

1. A subject who regains the cognitive ability to consent must be re-consented using standard consenting procedures.
2. In the event a subject has been initially consented by a surrogate, and a surrogate of higher priority subsequently notifies the investigator of that relationship to the subject, the investigator must defer to the higher priority surrogate's decision regarding whether the subject will continue to participate or to withdraw from the study.
3. Investigators shall describe to potential surrogates the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures, changes to the study, etc., in order to ensure that the surrogate will be willing to undertake these on-going responsibilities.

In the event that the surrogate dies, the subject must be re-consented subsequently upon any event that would otherwise trigger re-consenting the subject.

The IRB letter of approval will specifically document that the project complies with the provisions of California law for use of surrogate consent.

#### ***Procedures***

1. The Investigator will select appropriate individuals and methods for capacity determinations.
2. The IRB Chair and IRB members will determine what human subjects protections are appropriate to a study and to the needs of decision-impaired individuals, according to this policy. Verify during continuing review that the policy has been followed.
3. The IRB Administrator will document in the file that additional approval criteria in this section have been met.

***Applicable Regulations***

[American Psychiatric Association, "Guidelines for Assessing the Decision-making Capacities of Potential Research Subjects with Cognitive Impairments," American Journal of Psychiatry 155 \(1998\): 1649–50.](#)

[California Health and Safety Code, Section 24175 and 24178](#)

[National Bioethics Advisory Commission. Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity, December 1998.](#)

[VHA Handbook 1200.05](#)