

University of California, San Diego (UCSD) and Rady Children's Hospital – San Diego (RCHSD)
IRB Protocol Application
RESEARCH PLAN INSTRUCTIONS

These are instructions for filling out the Research Plan that is available in MS Word format from the IRB website: <https://irb.ucsd.edu>

The headings on this set of instructions correspond to the headings of the Research Plan.

General Instructions: Enter a response in for all topic headings.

Enter "Not Applicable" rather than leaving sections blank if the section does not apply to this project.

Version date:10/09

1. PROJECT TITLE:

Enter the project title here. It should match the title entered on the application and informed consent documents. Note: for funded grants (including VA), the application title must be the same as the grant title.

2. PRINCIPAL INVESTIGATOR:

Include Principal Investigator's title and department. This is for identification purposes, to match the Research Plan to the project application. The **complete list** of investigators and study personnel must be entered on the application. There can be only one Principal Investigator.

3. FACILITIES:

List all locations where the project will be done and any specialized facilities (e.g. MRI sleep lab, a specialty clinic, Day Surgery, pharmacokinetics room) that the project will use. Provide the name of the administrator for the specific facilities you will use who provided (will provide) approval. [Note all facility approvals must be in place at the time of IRB approval.]

4. ESTIMATED DURATION OF THE STUDY:

State how long each subject's participation will last. State the duration of the entire study (study initiation through closure).

5. SPECIFIC AIMS:

Provide a statement of the **specific aims** and **hypotheses** that serve as the basis for this protocol. Emphasize those aspects that justify the use of human subjects.

6. BACKGROUND AND SIGNIFICANCE:

Provide a succinct discussion of relevant background information and the rationale for the current study. Appropriate references should be included. [If this is a drug study and an Investigator's Brochure is not available for this study, include a summary of the pre-clinical/animal data and any relevant clinical data.]

7. PROGRESS REPORT/PRELIMINARY STUDIES:

If this is a **continuation application**, please provide a brief **summary of past experience** with this protocol including any untoward effects. List any publications that have resulted from this protocol. Continuation applications must be revised from the original application to reflect any changes in the research design and must describe progress made since the original application. Please note: Since the last review of this project, additional review and documentation requirements for IRBs may have been published by the Federal Office of Human Research Protections, and the current review will be performed in accord with these additional requirements. In some cases this leads to the necessity to add additional information or research subject protections to previously approved projects, or to amend previously approved consent forms. The review of this project may identify changes that are needed to comply with current human subjects protections guidelines.

8. RESEARCH DESIGN AND METHODS: (guideline length is 3-6 pages)

Describe the **research design**. State the primary and secondary variables or outcome measures. State the **procedures to be used** to accomplish the specific aims of the project. Define in clear terms exactly what will be done to the human subjects. **Be sure to indicate which procedures are routine care (standard of care) and which are experimental**. Where appropriate, identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. Also, indicate if there will be any identifiers associated with the specimens, records, or data or if they will be obtained anonymously.

If subjects are to be randomized, describe the randomization procedure and the treatment allocation concealment method.

Provide a **precise description of the planned data collection, data analysis and planned data interpretation**. This should include criteria for determining statistical significance and justification of sample size.

Inclusion of women and minorities must be addressed in all research protocols. For example, what is the study population of interest and where will subjects be recruited? What percentages of women and minorities have the condition under study and what percentage will be in your study? If inclusion of women or minorities is inappropriate, the scientific rationale for the study population must be explained and justified.

List potential biases or problems and how they will be minimized or addressed.

Clearly outline drug names and dosages to be utilized in this study in this section. Clearly explain if these drugs are FDA-approved for this subject population and for this purpose. If the study involves an IND (IND or compassionate use) or an IDE (IDE or HDE), please provide a copy of the correspondence from the FDA.

Copies of questionnaires, survey instruments, testing instruments must be submitted with the application.

9. HUMAN SUBJECTS:

Describe the characteristics of the proposed subject population; **including the total number you expect to accrue at this site (and total number), age, sex, ethnic background** and health status. Identify the criteria for inclusion and exclusion of any subpopulation. Explain the rationale for using participants from vulnerable groups, such as fetuses, pregnant women, children (specify whether **wards** will be included), human *in vitro* fertilization, groups with known cognitive impairment, or institutionalized individuals. Include a description of the methods that will be used to identify prospective subjects. Please be aware that the IRB is required to make a specific determination that the selection of subjects is **equitable**. For research involving persons under the age of 18 that is conducted at the VA, a VA Central Office waiver must be obtained prior to commencing the study at the VA.

Also address whether **non-English speaking subjects** will be included. A scientific justification must be provided for their exclusion.

10. RECRUITMENT AND SCREENING:

Describe the plans for recruitment of subjects. State how potential subjects will be identified for recruitment, where the recruitment will occur, and who will do the recruiting. The text of all recruitment materials (flyers, advertisements, letters, etc.) must be reviewed and approved by the IRB before it can be used for the study. All changes to recruitment material must also be reviewed and approved by the IRB before it can be distributed.

Also detail the screening procedures. Specifically state what procedures are involved and when consent is obtained.

Note: If this is a VMRF study, additional recruitment material guidelines and approvals are required from VMRF. VMRF approval-for-submission must be secured prior to submission to HRPP. If the study is a VA study or is administered by the VMRF, the P.I. must be in receipt of a VA Form 10-1223, indicating that the study has been reviewed and approved by the VA Research and Development Committee, prior to beginning enrollment.

11. INFORMED CONSENT:

Describe the **consent and assent procedures** to be followed, including the circumstances under which consent/assent will be obtained, who will seek it, and the methods of documenting consent. The text of all communications with prospective subjects must be submitted for review.

For studies involving minors that pose greater than minimal risk, and no prospect for direct benefit, consent must be obtained from both parents, per 45 CFR CFR 46.408 (“where research is covered by [§46.406](#) and [§46.407](#) and permission is to be obtained from parents, both parents must give their permission 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.”)

Follow the standard Rady Children’s, UCSD, VA, and/or VMRF formats that are available online at the HRPP website <https://irb.ucsd.edu>. Note: **Consents must be single-sided and written in lay language and the second-person.**

Special circumstances:

- a) California law AB2328 on Surrogate Consent for Research became effective January 1, 2003. If you intend to have the option of consent for participation by someone other than the research subject (ie., a “Legally Authorized Representative.”) you will need to supply in Section 28 of the application a description of the specific procedures that will be used to obtain surrogate consent. California law requires a documented assessment of decisional capacity as part of the procedures for obtaining surrogate consent. See Section 28 of these instructions for guidelines on how to do this.
 - b) If your subject population is one whose decision-making capacity may be impaired, detail what method(s) you will use to make certain that they can give effective informed consent. This method(s) must be clearly articulated in the protocol.
 - c) When to create and use UCSD, UCSD-RCHSD, VA and VMRF consents: The general principal governing which consent to be used is that the funding source and location of study determines which consent format to use. This is due primarily to differences in the “harm clause” that explains which institution is fiscally responsible for care delivered to treat research injuries.
1. Use the VA **10-1086 Informed consent document** when the study is a VA funded grant or a VASDHS unfunded study, whether or not the subject is a veteran.
 2. Use a **VMRF Informed consent document** when the funds for the study are being administered through VMRF, whether or not the subject is a veteran.
 3. Use a **UCSD Informed consent document** when the funds for the study are being administered through UCSD grants and contracts, whether or not the subject is a veteran.
 4. Use **both UCSD and VMRF consent forms** if a study is commercially sponsored and being conducted at UCSD facilities and at the VA. (Note: Clinical Trial Agreements (CTAs) will be needed at both sites.)
 5. For PI-initiated research studies conducted in collaboration with commercial sponsors, contact the appropriate UCSD Office of Contract and Grant Administration (OCGA) analyst at (858) 534-9884 or the Rady Children’s Hospital Center for Pediatric Clinical Research (CPCR) at (858) 966-8047 regarding the terms of the agreement and appropriate harm clause language.
 6. Use a **UCSD-RCHSD** consent form if the PI is a UCSD employee, and/or the grant/contract is being administered through UCSD and/or subjects are being seen at RCHSD.

Proprietary Interest Disclosure

Since the Moore v. Regents decision was rendered by the California Supreme Court, informed patient consent for University of California research projects now requires that ... (a) "a physician must disclose personal interests *unrelated to the patient's health*, whether research or economic, that may affect the physician's professional judgment; and (b) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of confidentiality."

The following wording for consent forms covering the use of human tissue or fluids:

"Your _____ may also be used in additional research to be conducted by the University of California personnel and the biotechnology company collaborating in the research, _____. This _____ and its derivatives may have significant therapeutic or commercial value. You will not receive any benefits from such uses.

You consent to such uses. ___Yes, I consent. ___No, I do not consent." If the study involves children, please replace “your” and “you” with “Your and your child,” “You and your child” or “your child” accordingly.

In disclosing your proprietary interest and research interest in the consent you may do so in general terms and make certain to include the nature of the interest. Examples of disclosure statements are included in section #26 of this application.

12. ALTERNATIVES TO STUDY PARTICIPATION:

List alternatives to study participation that are reasonably available that may be of benefit to the potential subject. If there are no therapeutic alternatives (no current treatment) or if this is a research study without prospect of direct benefit, state that the only alternative is not to participate in the study. This information should also be contained in the consent form.

13. POTENTIAL RISKS:

Describe and assess any potential or known risks - physical, psychological, social, legal or other, and assess their likelihood and seriousness. If data is available, estimate the probability that a given risk may occur, its severity and its potential reversibility. If the study involves a **placebo** and/or a **washout** period, the risk(s) related to these must be addressed in both the protocol and the consent. If the study may pose any known or unknown risk to a fetus or nursing infant, this must be stated here and in the consent. If there may be a potential for unforeseeable risks associated with participation in this study, this should also be stated, here and in the consent. If the potential for subjects to become upset, require psychological, or medical attention, as a result of the research procedures, a means of supplying this attention must be addressed.

14. RISK MANAGEMENT PROCEDURES:

Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Specify steps to be taken to guard the anonymity of subjects and/or the confidentiality of their responses, and who will have access to the data. If there will be a key to coded information, describe the means of protecting the key. Indicate what personal identifying indicators, if any, will be kept on subjects. Specify procedures for storage and ultimate disposal of personal information.

Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject, e.g. an unblinded co-investigator in a high risk Phase I study. Also, where appropriate, discuss the provisions for monitoring the data collected to ensure the safety of subjects. Explain if the study has a Data Safety Monitoring Board (DSMB).

Note: if this is a multi-centered NIH-sponsored trial, DSM plans are now required as part of the protocol. NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for Phase III clinical trials involving interventions that entail potential risk to the participants. NIH policy requires that investigators submit a general description of the Data and Safety Monitoring Plan for clinical trials (biomedical and behavioral intervention studies) as part of the research application. In developing the Data and Safety Monitoring Plan, refer to the NIH Policy For Data and Safety Monitoring at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html> or <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>.

A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring, and how Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with IND or IDE regulations. Although no specific page limitation applies to this section of the application, be succinct.

15. POTENTIAL BENEFITS:

Discuss those benefits to be gained by the individual subject, as well as those benefits that may accrue to society in general. If there is no direct benefit to the subject, this must be stated. *Note: Overly optimistic statements of benefit should be avoided. Reimbursement/payment and provision of investigational/experimental study drugs do not fall under the benefits section.*

16. RISK/BENEFIT RATIO:

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

17. EXPENSE TO SUBJECT:

If the investigation involves the possibility of added expense to the subject (longer hospitalization, extra studies, etc.) indicate in detail how this will be handled. In cases where the FDA has authorized the drug or device company to charge

the patient for the experimental drug or device, a copy of the authorization letter from the FDA or sponsor must accompany the application. Final approval will not be granted until the IRB receives this documentation.

There are very limited circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, provide a justification as to why this is appropriate and acceptable. For example, if the study involves treatment that is documented standard of care and not investigational, state so. In these cases, the protocol and the consent should clearly define what is standard of care and what is research.

18. COMPENSATION FOR PARTICIPATION:

Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.

19. PRIVILEGES/CERTIFICATIONS/LICENSES AND ROLES OF THE RESEARCH TEAM:

This section should provide a detailed explanation that specifically outlines each member of the research team's responsibilities. It should specify which individuals are privileged/certified or licensed, and at what sites, to perform the procedures in the protocol. Examples include: Dr. 'X' is a Ph.D. who will be conducting the data analysis for the study, Dr. 'Y' who is an M.D., has medical privileges at the VA and UC Medical Centers to perform the biopsy. Dr. 'Z' who is an M.D., will only be conducting the 'abc' procedure for which she has privileges only at the UCSD Medical Center. If individuals are not privileged, to perform the procedures as described in the protocol, explain in detail the plan to deal with this issue. A response such as "Everyone on this study is privileged" cannot be accepted.

Please note: An investigator or co-investigator cannot be listed on a VA/VMRF study if s/he does not have medical privileges at the VA if s/he is participating in the research at the VA site. All studies to be conducted utilizing VA resources must include a VA Responsible Investigator (RI) on the study.

20. BIBLIOGRAPHY:

List up to five relevant articles that the IRB Committee can use to provide necessary background for the protocol. Do not append an extensive NIH-grant-style bibliography.

21. INDUSTRY-SPONSORED OR COLLABORATING STUDIES:

If this is a drug or device company sponsored study, document the roles of the P.I. and/or co-investigators in the initiation and design of the protocol and access to data. State whether a contract (or subcontract) is in process and a statement regarding the type of support that is being provided (drug supply, study costs). Indicate patent ownership, if known. List the name of the person or organization that holds the Investigational New Drug (IND) or Investigational Device Exemption (IDE). If an IND/IDE has been issued, provide that number on the face sheet of this application.

In the case that a study is investigator-initiated, this section should clearly describe the nature of the collaborating entity's involvement. An example of this is: "Company 'X' is providing the study drug only and a research agreement (RA) has been negotiated with OCGA or with the or the CPCR to cover this involvement. This RA allows the company to review study data and have access to all participant's study records. The company will provide no coverage for any adverse events associated with the study because..."

Please note: All research team members listed on the 1572 must be listed on the application.

22. OTHER FUNDING SUPPORT FOR THIS STUDY:

Clearly detail if this project is supported by the NIH or another source. Provide the grant number and inclusive dates of support on the face page and in this section. State if the grant is going through UCSD, RCHSD, VA and/or VMRF as a grant or sub-contract. Please provide the name and phone number for the fiscal contact person or analyst handling the grant.

If you have indicated on the face sheet that there is no funding support for this project, you will need to explain in detail how the project is to be supported.

If this project is administered by the **VMRF** note this on the face page and in this section of the protocol narrative. Please note that there is different indemnification language that must be used in the consent document if this study is administered by **VMRF**. All VA and VMRF studies must be approved by the VA Research and Development Committee and the P.I. must have received a VA 10-1223 form prior to commencing the study at the VA.

23. BIOLOGICAL MATERIALS TRANSFER AGREEMENT:

If the protocol involves any tissue or biological fluids, etc. of the subject being sent to another institution, a Biological Materials Transfer Agreement (BMTA) may be needed. If the material is being sent to either the organization/entity sponsoring the study for use in the study or a laboratory as part of the study, a BMTA is not necessary. If the material is being sent to any organization/entity for use involving its own purposes (outside the study), a BMTA must be in place. This should occur concurrently with your IRB application. For further information concerning the BMTA, please contact the RCHSD Office for Human Subjects Protection at (858) 966-4008 or the UCSD Office of Contracts and Grants Administration at (858) 534-9884.

If a drug or human blood or tissue is to be transferred to the University, make sure that a Human Subjects Protocol has been, or is in the process of being, approved by the University's Human Subjects IRB. Include the Human Subjects Protocol Number on the Material Transfer Agreement Questionnaire. Also ensure that the providing organization identified in the Material Transfer Agreement Questionnaire is named in the Human Subjects Protocol.

24. INVESTIGATIONAL DRUG FACT SHEET:

If the study involves any investigational drug(s), an Investigational Drug Fact Sheet must be filled out by the investigator and included in the application packets. A separate sheet needs to be filled out for each investigational drug. **IRB approval for the study is contingent upon this occurring.** Please explain how the investigational drug will be handled (pharmacy, location, etc.).

25. IMPACT ON STAFF:

If the conduct of the study involves the nursing staff from UCSD and/or RCHSD staff (nursing, laboratory, pathology, pharmacy, medical records), indicate what additional time or staff skills are required. Specify in the project plan whether there is a budget provided for staff training and participation in the study, and whether there are plans for "in-service" training. Projects done in an inpatient or outpatient setting require an affirmative statement that the study plan has been discussed with the appropriate nursing supervisor and that the nursing service approves.

26. CONFLICT OF INTEREST (COI)

In this section, for projects that are funded, either completely or partially, by commercial sponsors please note whether or not a financial relationship between any of the investigators on the project and the sponsor. In this section, put a narrative description of what this relationship is for all investigators and other key personnel on the project. Examples of financial relationships include consulting, participation in speakers bureaus, stock or stock option ownership, or service on advisory boards or the board of directors of a company, or service as a company officer.

In addition, where there is a commercial sponsor for a UCSD project, a Form 700U form "PRINCIPAL INVESTIGATOR'S STATEMENT OF ECONOMIC INTEREST" should be completed by the PI and all co-investigators on the study and submitted to the UCSD Conflict of Interest Office. Form 700U and instructions for completing it are available on the UCSD Office of Contracts and Grants website <http://ocga2.ucsd.edu>. Effective May of 2003, the Form 700U should be sent only to the COI office and not included in the IRB application, making it essential that financial relationships be described as a narrative in this section.

*Note: If none of the study members are affiliated with UCSD the Form 700U is not required. However, indicate a positive interest if any of the study members (self, spouse or dependent children) have a possible conflict of interest with the sponsor:

- Equity & ownership > \$10,000 or 5%;
- Direct/indirect ownership, (includes publicly traded stock) > \$10,000;
- Position as a director, officer, partner, trustee, or employee of any management position held;
- Payment (consultant fees, honoraria, grant payments) > \$10,000.

For projects that do not have a source of funding, but involve a drug or device disclose if a COI exists.

____ An intellectual property interest, e.g., a patent (actual, planned, or applied for) or a copyright for software assigned or to be assigned to a party other than the Regents.

If this is a federally-sponsored project for which a COI disclosure has been filed indicating that the PI or any key personnel have a COI, a copy of the COI concurrence letter must be provided with the application.

All actual and potential Conflicts of Interest must be disclosed in the consent documents. Examples of disclosures include: "Dr. X is a paid consultant for Company Y, the sponsor of this study;" or "Dr. X owns stock in Company Y, a collaborator in this research study." If the PI is listed on a patent, one example of acceptable disclosure would be: "Dr. X developed the Y device to be used in this study and has a personal interest in the device. Dr. X and the *University of California or Rady Children's Hospital* may benefit should its use be determined beneficial. This disclosure is made so that you can determine if this relationship will affect your willingness to participate in this study."

27. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

Cancer-related protocols with a UCSD investigator must follow the **National Cancer Institute (NCI) format**. Also, remember when submitting cancer protocols an **additional 10 copies of the application and one copy of the formal protocol must be sent to the Cancer Sub-Committee, ATTN: PRMC, 0698 by the deadline date**. (This is also true for replacement applications and substantive revisions of an approved protocol). Please make certain that the formal protocol has the standard cover page for UNIVERSITY OF CALIFORNIA, SAN DIEGO CANCER CENTER INSTITUTIONAL PROTOCOLS.

28. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

Surrogate Consent and Decisional Capacity Assessment are two related topics. An investigator may employ Decisional Capacity Assessment for either of two purposes:

- 1) in a study where the study population being recruited may reasonably be expected to have decisional impairment, an investigator may use Decisional Capacity Assessment to demonstrate that all participants who have consented for participation have the capacity to consent for themselves;
- 2) in a study where the investigator wishes to have the option of using a "Legally Authorized Representative" of the subject to provide surrogate consent, Decisional Capacity Assessment is required by California law as a component of the surrogate consent process.

Detailed plans for performing Decisional Capacity Assessment and/or for obtaining Surrogate Consent should be entered in this section of the application, or the words "Not Applicable" should be entered. A copy of all forms that will be used to document decision-making capacity at the time of consent should be included with the application.

Procedures for Decisional Capacity Assessment were developed in 2002 by a UCSD task force on this topic, and are available on the HRPP website (<http://irb.ucsd.edu/decisional.shtml>) along with examples of post-consent assessment instruments that can be adapted to an investigator's own research project.

Investigators should be aware that the IRB may, depending upon the nature of the proposed research and its subject population, require Decisional Capacity Assessment as part of the research plan.

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." Surrogate consent for participation in a research study should be employed only to the extent that it is consistent with federal and state laws and guidance pertaining to protecting human subjects participation in research. Consistent with guidelines provided by

the University of California Office of the President (available on the HRPP website at <http://irb.ucsd.edu/surrogate.shtml>) the IRB will use the following criteria when determining whether to permit the use of surrogate consent for participation in a research study:

- 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.

Steps required by California AB2328 for obtaining Surrogate Consent

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 (see UCSD Procedures for Decisional Capacity Assessment for various approaches to doing this step. Include in this section of the application which of the approaches available will be employed by this 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:

- Has reasonable knowledge of the subject;
- Is familiar with the subject's degree of impairment;
- Is willing to serve as the substitute decision-maker;
- Understands the risks, potential benefits, procedures and available alternatives to research participation;
- 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 keep the signed form along with a copy of the consent. In addition, the researcher must keep a copy of this 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 on an inpatient psychiatric ward, inpatients of a mental health facility, 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:

- A subject who regains the cognitive ability to consent must be re-consented using standard consenting procedures.
- 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.
- 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.

29. HIPAA

Address whether or not protected health information [PHI - any identifiable health information (e.g., medical record information, knowledge of patient condition, or any information that can reasonably identify a patient)] will be used, disclosed, accessed or created throughout this study. If PHI will be used, disclosed, accessed or created, either include (or state) that a HIPAA authorization form https://irb.ucsd.edu/CHHC-UCSD_HIPAA_Authorization_form.doc will be signed by the subject/subject's parent/guardian at the time consent is obtained, or whether a waiver of HIPAA authorization https://irb.ucsd.edu/CHHC_HIPAA_waiver_request.doc is requested (e.g., retrospective chart review with no patient contact).

If PHI will be accessed for recruitment (e.g., confirm meets eligibility criteria, transfer contact information from treating physician to coordinator after verbal approval from potential subject) a waiver of HIPAA authorization will also be required.

If you will maintain a database for future use (uses other than those specifically related to this study), this must be clearly stated in this section of the research plan, the consent form and the HIPAA authorization form (if applicable). Specify what information will be retained in this database and provide examples of the potential future uses of the information.

For additional information regarding HIPAA refer to the HRPP web site at <http://irb.ucsd.edu/hipaa.shtml>.