



# UC San Diego

## Policy & Procedure Manual

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### I&R POLICY AND ORGANIZATION

#### Section: 100-5

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## PROTECTION OF HUMAN RESEARCH SUBJECTS

### I. PREAMBLE

The University of California, San Diego and the VA San Diego Healthcare System, hereinafter referred to as "institution" hereby gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects, [45 CFR Part 46](#), as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56 FR 28003) as Subpart A, and as may be further amended during the approval period for this Assurance.

### II. STATEMENT OF APPLICABILITY, DEFINITIONS, PRINCIPLES, AND GENERAL POLICIES

#### A. Applicability

1. This assurance is applicable to all federally funded research involving human subjects, and all other activities which even in part involve such research if one or more of the following apply:
  - a. the research is sponsored by this institution, or
  - b. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
  - c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
  - d. the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.
2. This assurance is applicable to all research involving human subjects, and all other activities which even in part involve such research if one or more of the following apply:
  - a. the research is conducted by or under the direction of any employee or agent of the VA San Diego Healthcare System (VASDHS) in connection with his or her VASDHS responsibilities, or
  - b. the research is conducted by or under the direction of any employee or agent of the VASDHS using any property or facility of the VASDHS, or
  - c. the research involves the use of the VASDHS's non-public information to identify or contact human research subjects or prospective subjects.
3. No categories of research involving human subjects are exempted from the provisions of this assurance.
4. Components of this institution are bound by the provisions of this Assurance. Those components which can be expected to participate in human subject research sponsored by DHHS or other Federal departments or agencies for which this Assurance will apply are identified in the Assurance and will be revised as changes occur and revisions forwarded to the Office for Human Research Protections (OHRP).
5. This Assurance must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects when appropriate for the research in question and therefore applies to all human subject research so sponsored. Research that is neither conducted nor

supported by a Federal department or agency but is subject to regulation as defined in [Section 102\(e\)](#) must be reviewed and approved, in compliance with Sections [101](#), [102](#), and [107 through 117](#).

**B. Definitions**

1. Research is defined in [45 CFR 46](#) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
2. Human Subject is defined in [45 CFR 46](#) as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the person or (2) identifiable private information."
3. IRB is defined in [45 CFR 46](#) as "an Institutional Review Board established in accord with and for the purposes expressed in this policy."
4. IRB approval is defined in [45 CFR 46](#) as "the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements."

**C. Ethical Principles**

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: [Ethical Principles and Guidelines for the Protection of Human Subjects of Research \[the "Belmont Report"\]](#)), regardless of whether the research is subject to Federal regulation or with whom conducted or with whom conducted or source of support (i.e., sponsorship).
2. All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the DHHS Secretary.

**D. Institutional Policy**

1. All requirements of [Title 45, Part 46, of the Code of Federal Regulations \(45 CFR\)](#) will be met for all applicable DHHS-supported research, and all other human subject research regardless of sponsorship. Federal (all departments and agencies bound by the Federal Policy) funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.
2. It is the policy of this institution that all research covered by this Assurance will be reviewed and approved by an institutional review board (IRB) which has been established under a Federalwide Assurance (FWA). The involvement of human subjects in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol *and* informed consent has been obtained from the subject or the subject's legal representative (see Sections [111](#), [116](#), and [117](#)).
3. This institution assures that before human subjects are involved in research covered by this Assurance, the IRBs will give proper consideration to:
  - a. The risks to the subjects.

- b. The anticipated benefits to the subjects and others.
  - c. The importance of the knowledge that may reasonably be expected to result, and
  - d. The informed consent process to be employed.
4. Certification of IRB review and approval for all Federally-sponsored research involving human subjects will be submitted to the Office of Contract and Grant Administration (OCGA) for forwarding to the appropriate Federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of IRB review to DHHS or other Federal departments or agencies for which this Assurance applies. As required under [Section 119](#), the IRB will review and recommend approval for involvement of human subjects in Federal research activities for which there was no prior intent for such involvement, but will not permit such involvement until certification of the IRB's review and approval is received by the appropriate Federal department or agency
5. Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. This institution will ensure that such other institutions and investigators not bound by the provisions of this Assurance for DHHS sponsored research will satisfactorily assure compliance with [45 CFR 46](#), as required (See III.A.4. and III.C.3.) as a prior condition for involvement in human subject research which is under the auspices of this institution (see II.A.) Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP) of DHHS for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory institution to this Assurance.
6. This institution will ensure that any of its affiliates materially engaged in the conduct of non-federally sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed (see II.C.)
7. This institution will comply with the requirements set forth in [Section 114](#) of the regulations regarding cooperative research projects. When research covered by this Assurance is conducted at or in cooperation with another entity, all provisions of this Assurance remain in effect for that research. This institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another DHHS FWA. Such acceptance must be (a) in writing, (b) approved and signed by an official of this institution's Office of Contract and Grant Administration, and (c) approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed understanding will serve as an addendum to this Assurance and will be forwarded to the OHRP of DHHS by the OCGA.
8. This institution will exercise appropriate administrative overview to insure that the institution's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with this Assurance.
9. This institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

**III. RESPONSIBILITIES**

**A. Institution**

1. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state, or local laws as they may relate to such research.
2. This institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization (see [45 CFR 46](#) Subpart B), (2) prisoners (see [45 CFR 46](#) Subpart C), (3) children (see [45 CFR 46](#) Subpart D), (4) the cognitively impaired, or (5) other potentially vulnerable groups.
3. This institution, including all its named components, acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this Assurance.
4. This institution is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its standing affiliates and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.
5. This institution is responsible for ensuring that no affiliates cooperating in the conduct of federally sponsored research for which this Assurance applies do so without an appropriate assurance of compliance and satisfaction of IRB certification requirements.
6. In accordance with the compositional requirements of [Section 107](#), this institution has established the IRBs in accordance with the requirements on the Protection of Human Subjects ([45 CFR 46](#)), including its relevant subparts. Certain research supported by the U.S. Department of Education will be reviewed in accordance with the requirements of [Title 34 CFR](#) Parts [350](#) and [356](#) which require that the IRBs include one person who is primarily concerned with the welfare of handicapped children or mentally disturbed persons.
7. This institution will provide both meeting space and sufficient staff to support the IRB's review and recordkeeping duties.
8. This institution recognizes that involvement in research activities of any OHRP-recognized Cooperative Protocol Research Programs will involve additional reporting and recordkeeping requirements related to human subject protection.

**B. Human Research Protections Program (HRPP)**

1. The HRPP will receive from investigators, through their supervisors, all research protocols which involve human subjects, keep investigators informed of decisions and administrative processing.
2. The HRPP will make the preliminary determination of eligibility for expedited review procedures (see [Section 110](#)). Expedited review of research activities will not be permitted where full board review is required (e.g., provision of emergency medical care which also constitutes the conduct of more than minimal risk research).
3. The HRPP will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

4. The HRPP will maintain and arrange access for inspection of IRB records as provided for in [Section 115](#).
5. The HRPP is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subject.
6. The HRPP will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of [45 CFR 46](#), regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal policies and guidelines related to the involvement of human subjects in research.
7. The HRPP will report promptly to the IRBs, appropriate institutional officials, the Office for Human Research Protections (OHRP), and any other sponsoring Federal department or agency head:
  - a. Any unanticipated problems involving risks to subjects or others,
  - b. Any serious or continuing noncompliance with the regulations or requirements of the IRB, and
  - c. Any suspension or termination of IRB approval for research.
8. The HRPP assumes responsibility for ensuring conformance with special reporting requirements for any OHRP-recognized Cooperative Protocol Research Programs in which the signatory institutions participate.
9. The HRPP will be responsible for procedural and recordkeeping audits not less than once every year for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution.

**C. Office of Contract and Grant Administration (OCGA)**

1. OCGA will review all funding proposals and decide whether the institution shall support or sponsor such research. If approved by the IRB, but not permitted by the institution, OCGA will promptly convey notice to the investigator and the HRPP. Neither OCGA nor any other office of the institution may approve a research activity that has been disapproved by the appropriate IRB.
2. OCGA will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.
3. OCGA will ensure (a) solicitation, receipt, and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB review (where appropriate) for all affiliates to this institution, and (b) subsequent submission of these documents to the proper authorities as a condition for involvement in human subject research activities sponsored by DHHS or any other Federal department or agency for which this Assurance applies.
4. OCGA will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the

protection or research subjects at least document mechanisms to implement the equivalent of ethical principles to which this institution is committed (see Part II.C.).

5. When an IRB of this institution accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this Assurance, OCGA will obtain and retain a Noninstitutional Investigator Agreement (NIA) to document the investigator's commitment to abide: (1) by the same requirements for the protection of human research subjects as does this institution and (2) the determinations of the IRBs.
6. OCGA will ensure compliance with the requirements set forth in this Assurance and [Section 114](#) regarding cooperative research projects as applicable under the UCSD FWA. In particular, where the IRB of another institution with a DHHS FWA is relied upon, OCGA will ensure documentation of this reliance (a) in writing, (b) approved and signed by the OCGA, (c) approved and signed by the correlative officials of each of the other cooperating institutions, and (d) retained by OCGA for at least three years past completion of the related research project. Where an agreement between FWA IRBs is planned, OCGA will forward a copy of the required signed understanding to OHRP for inclusion in this Assurance as an addendum.

**D. Institutional Review Board (IRB)**

1. The IRBs will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will  
  
determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.
2. IRB decisions and requirements for modifications will be promptly conveyed to investigators, in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.
3. Initial and continuing convened IRB reviews and approvals will occur in compliance with [45 CFR 46](#) and provisions of this Assurance for each project. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings.
4. The IRBs will observe the quorum requirements of [Section 108\(b\)](#). This institution's IRBs have effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeable contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of Sections [103\(d\)](#), [107\(a\)](#), [111](#), and [116](#).
5. The IRBs will determine, in accordance with the criteria found at [45 CFR 46.111](#) and Federal policies and guidelines for involvement of human subjects in HIV research, that protection for human research subjects are adequate.
6. The IRBs will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of Sections [116](#) and [117](#). The IRBs will have the authority to observe or have a third party observe the consent process.

7. Where appropriate, the IRBs will determine that adequate additional protection are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C and D of [45 CFR 46](#). The IRBs will notify OHRP promptly when IRB membership(s) is modified to satisfy requirements of [45 CFR 46.304](#) and when the IRB fulfills its duties under [45 CFR 46.305\(c\)](#).
8. Scheduled meetings of the IRBs for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. An IRB may be called into an interim review session by the Chairperson at the request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any subject.
9. The IRBs will prepare and maintain adequate documentation of their activities in accordance with [Section 46.115](#) and in conformance with HRPP requirements.
10. The IRBs will forward to appropriate institutional officials any significant or material finding or action, at least to include the following:
  - a. Any unanticipated problems involving risks to subjects or others,
  - b. Any serious or continuing noncompliance with the regulations or requirements of the IRB, and
  - c. Any suspension or termination of IRB approval.
11. In accordance with [Section 109](#), the IRBs will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
12. The IRBs for this institution will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members. The IRBs include those who are identified as knowledgeable about any affiliate institution having entered into an Inter-Institutional Amendment or other Assurance when relying on one or more of the IRBs of this institution.
13. The IRBs will act with reasonable dispatch, upon request, to provide full board review of protocols of OHRP-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research.

Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.
14. Certifications of IRB review and approval will be forwarded through the OCGA to the appropriate Federal department or agency for research sponsored by such departments or agencies.

**E. Research Investigators**

1. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.



2. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the HRPP.
3. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
4. Research investigators are responsible for reporting progress of approved research to the HRPP, as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.
5. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.
6. No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see [Section 116\[f\]](#)). However, such activities will not be counted as research nor the data used in support of research.
7. Research investigators will advise the IRB, OCGA and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP- approved Assurance prior to involvement of such persons as human subjects in those research protocols.

**F. Affiliated Institutions and Investigators**

1. Each affiliate to this institution that is involved in DHHS-sponsored research activities must provide to the HRPP an appropriate written assurance of compliance with the Belmont Report and [45 CFR 46](#) (or equivalent protection if a foreign site).
2. Each affiliate institution must respond to a request by the HRPP of this institution for an Inter-Institutional Amendment or for an FWA, when and as appropriate, whichever is more suited to the circumstances.
3. Each non-institutional affiliate (e.g., a private practice physician not otherwise an employee of this institution or who otherwise would not ordinarily be bound by the provisions of this Assurance) who is involved in human subject research of this institution must respond to a request by the HRPP of this institution for a Noninstitutional Investigator Agreement when required.
4. Performance sites that are not legally inseparable components of this institution (whether an institutional or non-institutional affiliate) are not authorized to cite this Assurance.

**IV. SIGNATURES**

**A. Institutional Endorsements**

1. Primary Authorized Institutional Official  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Name: Gary Firestein, M.D.  
Title: Dean, Translational Medicine  
Institution: University of California, San Diego  
Address: 9500 Gilman Drive 0656  
La Jolla, CA 92093-0656  
Phone: (858)-534-2606  
\_\_\_\_\_
  
2. Primary Contact  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Name: Michael Caligiuri, Ph.D.  
Title: Director, Human Research Protections Program  
Institution: University of California, San Diego  
Address: 9500 Gilman Drive 0052  
La Jolla, CA 92093-0052  
Phone: (858) 455-5050  
\_\_\_\_\_
  
3. Other Authorized Institutional Official  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Title: \_\_\_\_\_  
Institution: VA San Diego Healthcare System  
Address: 3350 La Jolla Village Drive  
La Jolla, CA 92161  
Phone: \_\_\_\_\_  
\_\_\_\_\_
  
4. Other Primary Contact  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Institution: VA San Diego Healthcare System Address: 3350 La Jolla Village Drive  
La Jolla, CA 92161  
Phone: \_\_\_\_\_  
\_\_\_\_\_

\*\*\*\*\*

**FOR DHHS USE ONLY**

**B. Office for Human Research Protections, DHHS Approval**

1. DHHS Recommending Official  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**University of California, San Diego Policy – PPM 100 - 5**  
**PPM 100 – 5 Protection of Human Research Subjects**

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Address: Office for Human Research Protections (OHRP)  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
Phone: (240) 453-6900

2. DHHS Approving Official

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Address: Office for Human Research Protections (OHRP)  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
Phone: (240) 453-6900

[Please Resubmit as Changes Occur]

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# UC San Diego

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### I&R POLICY AND ORGANIZATION

#### Section: 100-5 APPENDIX A

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### APPENDIX A

COMPONENTS WHICH ARE LEGALLY INSEPARABLE FROM EACH DESIGNATED SIGNATORY INSTITUTION AND ARE AUTHORIZED TO CITE THIS FWA OR PARTICIPATE IN RESEARCH OF THE SIGNATORY

Names, Cities, and States

Signatory Institution #1 (i.e., Primary): \_\_\_\_\_

Components Authorized to Cite FWA

_____	_____
_____	_____
_____	_____

Signatory Institution #2: \_\_\_\_\_

Components Authorized to Cite FWA

_____	_____
_____	_____
_____	_____

Signatory Institution #3: \_\_\_\_\_

Components Authorized to Cite FWA

_____	_____
_____	_____
_____	_____

Signatory Institution #4: \_\_\_\_\_

Components Authorized to Cite FWA

_____	_____
_____	_____
_____	_____