I&R POLICY AND ORGANIZATION
Section: 100-5
Effective: xx/xx/~~2019~~2021
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Issuance Date: XX/XX/2021~~XX~~
Issuing Office: Office of IRB Administration

PROTECTION OF HUMAN RESEARCH SUBJECTS

SCOPE

This policy applies to the following in their roles overseeing, reviewing or conducting UC San Diego human subjects research:

- the Institutional Official for protection of human subjects
- Institutional Review Boards (IRBs)
- Researchers (and any Staff, Students or other individuals working under their direction)
- Department Chairs
- Office of IRB Administration (OIA), *formerly known as the Human Research Protections Program*

To the extent that they incidentally oversee human subjects research as part of broader duties, other UC San Diego offices, committees or personnel should be aware of this policy and collaborate with the entities listed above in the protection of human subjects.

All of the above have a shared commitment and responsibility to protect the rights and welfare of research subjects and together constitute the UC San Diego Human Research Protection Program (HRPP).

POLICY SUMMARY

UC San Diego and its employees share the responsibility to protect research subjects by following the ethical principles of the *Belmont Report* (1979) as operationalized by applicable regulations. Those principles are:

- Respect for Persons (recognizing the personal dignity and autonomy of individuals and providing special protection for those with diminished autonomy)
- Beneficence (minimizing possible risk of harm while maximizing anticipated benefits)
- Justice (fairness in the distribution of benefits and harms of research)

University of California policy applies ~~U.S. Department of Health & Human Services (DHHS) regulations (Title 45, Part 46, Subpart A of the Code of Federal Regulations)~~the *Common Rule* or commensurate protections to all human subjects research in which UC San Diego is engaged, regardless of funding source, funding status, the location, or scale of the research.

Additional regulations or policies may apply depending on, for example, whether Food and Drug Administration (FDA)-regulated products are involved, state laws cover particular populations, or a sponsor places additional conditions on funding. In the event that different applicable regulations and/or requirements conflict, the more restrictive regulations and/or requirements shall prevail.

This policy describes the authorities and responsibilities of various parties in protecting human subjects.

DEFINITIONS

Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the FDA under these sections of the FDCA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Common Rule: The Federal Policy for the Protection of Human Subjects as adopted into regulation by multiple federal agencies, including the Department of Health and Human Services (DHHS), National Science Foundation (NSF) and Department of Defense (DOD). For ease when citing specific provisions of the Common Rule, this policy and related policy, guidance, or procedure documents will generally refer to ~~DHHS~~ DHHS regulations at Title 45, Part 46, Subpart A of the Code of Federal Regulations (45 CFR 46).

Engagement: Generally, when UC San Diego is the prime awardee of funding for Human Subjects Research or when individuals exercise UC San Diego-granted authority or responsibility or perform UC San Diego-designated activities for human subjects research or obtain informed consent for human subjects research.

Exempt: Activities that constitute human subjects research but do not require IRB review because they have been administratively certified as 1) fitting into one or more exempt categories in applicable regulations, 2) not otherwise limited by regulation or policy, AND 3) meeting UC San Diego ethical standards as set out by OIA.

Human Research Protection Program: Those entities referred to by the Scope section of this policy (not to be confused with the former name of the OIA).

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens. For FDA-regulated research, "human subject" includes an individual (or their specimens in the case of device research) who is either the recipient of a test article or a control, whether patient or healthy individual.

Human Subjects Research: An activity that is either (a) "research" as defined below AND involves one or more "human subjects" as defined above or (b) a "clinical investigation" as defined above. "Clinical investigations" for treatment purposes (without research aims) are not considered "human subjects research" but this policy is applicable to the extent required by FDA regulations.

Institutional Official (IO): The official to whom the Chancellor delegates authority to sign assurances of, and to oversee the University's responsibility for, the protection of human subjects.

Institutional Review Board (IRB): A board established in accordance with and for the purposes expressed in the Common Rule and FDA regulations. For the purposes of this policy, a UC San Diego IRB is any IRB:

- operated by UC San Diego and designated under UC San Diego's Federalwide Assurance; or,
- operated by another institution but reviewing on behalf of the University with the agreement of the Institutional Official (or designee).

Principal Investigator (PI): The person working on behalf of UC San Diego who is responsible for the ethical conduct of the research and for carrying out the responsibilities described in this policy. Generally, in order to serve in this capacity for human subject protections an individual must be eligible under UC San Diego policy to submit proposals for extramural support and serve as PI. The protocol PI (for human subject protection purposes) does not have to be the same person as the award PI (for funding purposes).

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Undue influence: The deliberate use of improper means (such as intimidation, deception, bribery or exploitation of a vulnerability) to attempt or achieve improper ends (such as getting IRB staff or members to disregard legal responsibilities or institutional policy). Influence is not undue if it consists only of 1) persuading, disagreeing or criticizing, 2) using proper channels to change, or seek exceptions from, requirements or processes, or 3) disclosing, preventing or correcting improper or inefficient exercise of IRB authority.

POLICY STATEMENT

a) Overall Policy

1. UC San Diego and its employees share responsibility for protecting human subjects according to the requirements of applicable regulations and University policies.

2. University of California policy applies ~~DHHS regulations (Title 45, Part 46, Subpart A of the Code of Federal Regulations)~~the Common Rule or commensurate protections to all human subjects research in which UC San Diego is engaged.

3. This policy on Protection of Human Research Subjects applies to all human subjects research in which UC San Diego is engaged, regardless of funding source, funding status, or the location or scale of the Research.

4. Additional regulations or policies may apply. In case of conflict between applicable regulations, the more restrictive regulations prevail.

b) Commensurate Protections

Consistent with University of California systemwide policy, IO has the authority to~~may~~ approve ~~replace~~alternatives to specific ~~DHHS~~ Common Rule requirements for research that is not otherwise subject to the Common Rule (for example, provisions relating to the Federal government's role as a funder of research ~~are~~may be impossible to follow for unfunded research). The OIA

1. ~~IO~~ has the responsibility to ensure that such alternatives provide ~~with~~ commensurate protection~~s~~ to subjects and do not conflict with other applicable regulations. OIA will be responsible to maintain written documentation of the rationale and the approved alternative requirements.

~~1. for research that is not subject to the Common Rule.~~

2. For situations in which FDA regulations require IRB review of treatment and there are no research aims associated with such treatment (e.g., expanded access to investigational products; devices that may be marketed under Humanitarian Use Device status), the IRB will use a ~~IO may approve~~ modified ~~IRB~~ process consistent with prevailing FDA guidance for ~~to improve~~ efficiency while ~~so long as~~ensuring regulatory requirements are met. OIA will be responsible to maintain written documentation of the rationale and the approved modified process(es).

~~2.~~

c) Jurisdiction of the Human Research Protection Program

1. The UC San Diego HRPP covers all UC San Diego engagement in human subjects research ~~in which UC San Diego is engaged~~.
   ~~i.~~ The HRPP does not normally cover human subjects research in which UC San Diego is not engaged.
   ~~2.~~i. In rare cases, the IO may agree to extend the UC San Diego HRPP to cover unaffiliated individual investigators collaborating with UC San Diego. Such an arrangement requires a formal agreement and the active involvement of the UC San Diego PI and approval by the VCR.

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i. If another institution or unaffiliated research investigator relies on UC San Diego IRB review services, a documented arrangement is required.

4.ii. Unless explicitly agreed, UC San Diego is not responsible for on-site monitoring or conduct of the research by another institution or unaffiliated investigators relying on UC San Diego IRB review services.

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2. Researchers may might determine that their activities do not constitute human subjects research or do not engage UC San Diego, or researchers may request such a determination by OIA. , but oOnly OIA may provide official determinations on behalf of UC San Diego.
   i. The IO may also delegate such authority to other units, subject to appropriate training, documentation and audit standards (e.g., Health System QA/QI program). IO shall periodically assess delegation and may revoke or limit any such delegation.
   i.ii. Consistent with requirements of this policy, OIA shall provide guidance and tools so that decisions made by OIA or others are based on regulatory and University criteria and are made efficiently.

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d) Certification of Exemption from IRB Review

1. When UC San Diego is engaged in human subjects research, only individuals authorized under this Policy and not otherwise associated with the project may certify a project as exempt from IRB review.
   i. UC San Diego uses all permissible exemption categories ~~to the extent permitted by applicable regulation~~.
   ii. The IO may authorize creation of additional exemption categories for use with projects that are eligible for commensurate protections.
   iii. Any additional exemption categories shall be consistent with the nature and risk of the categories used in regulations.

2. Certification of exemption relates only to UC San Diego IRB review. Researchers (and individuals working on their behalf) may not express or imply that a certification exempts research from other applicable legal or institutional requirements.

3. IO and Director of, OIA are each authorized to:
   i. Certify projects as exempt from IRB review.
   ii. Accept another institution's exemption certification as sufficient for UC San Diego.
   iii. Permit the use of a validated self-certification tool.
   iv. Delegate the above authorities to appropriate ~~individuals~~units, ~~subject to~~contingent upon ongoing compliance with ~~appropriate~~ training, documentation and audit standards.
   v. Limit or revoke delegations of the above authorities for serious and/or continuing failure to comply with training, documentation and audit standards.

e) IRB Authority

1. For all proposed human subjects research in which UC San Diego is engaged that is not otherwise exempt from IRB review, a UC San Diego IRB has authority to:
   i. Approve or disapprove.
   ii. Require modifications in order to secure IRB approval.
   iii. Suspend or terminate its approval.
   iv. Observe (or have a third party observe) the consent process or the research.
   v. Grant waivers related to informed consent.
   vi. Grant waivers related to authorization under the Health Insurance Portability and Accountability Act (HIPAA).
   vii. Review eligible research via the expedited process described in 45 CFR 46.110 and 21 CFR 56.110.

2. Consistent with the *Responsibilities* section of this Policy, ~~The~~ IO may delegate additional authority~~ies~~ to the IRB (for example, authority to make determinations of "serious non-compliance"). ~~for the following:~~

i. For IRB-approved research, to determine whether non-compliance qualifies as "serious" or "continuing."
ii.2. For IRB-approved research, to determine whether a problem qualifies as an "unanticipated problem involving risks to subjects or others."

3. UC San Diego IRBs shall exercise the above authorities only in accordance with criteria established by federal or state regulation for human subject protections, the advice of University counsel and/or other campus authorities, University of California policy, and/or properly promulgated UC San Diego policy.
    i. When presented with matters outside their scope of authority, the IRBs shall ask the Director of OIA to refer such matters outside of their scope of authority to other appropriate offices when these situations are recognized.
    ii. The IRB Director of OIA and IRB Chairs will seek advice of University Counsel, the IO and/or the Vice Chancellor for Research (VCR) as needed.

4. To maintain high standards while providing effective and efficient service to researchers, UC San Diego IRBs make use of flexibility offered by regulations and policies. Examples include, but are not limited to, expedited review for minimal risk research or waivers related to consent.
    i. UC San Diego IRBs shall generally offer or grant flexibilities when appropriate for eligible studies even if a PI does not request such flexibilities. Some examples of this include, but are not limited to:
        1. Regardless of level of review requested by the Principal Investigator, the expedited review process may be used if the study is eligible.
        2. If a study is eligible for a waiver of signed informed consent but the study team fails to request this explicitly, the IRB may grant a waiver of signed informed consent, as appropriate.
    ii. UC San Diego IRBs retain the authority to make protocol-specific determinations that flexibility would not provide adequate subject protection.
        1. Such determinations must be documented, including protocol-specific justifications for the determinations.
        2. When such determinations are discussed at convened IRB meetings, the Chair shall call a specific vote. In order for the proposal to pass, a majority of the quorum must approve the proposal.

5. When reviewing on behalf of another institution, a UC San Diego IRB:
    i. Mmay exercise additional authorities explicitly granted by that institution in its policies and/or in the reliance agreement.
    ii. Mmay be prohibited from exercising authorities e(1)v-vii and e(2) above.
    iii. Sshall apply local requirements of that institution and/or the research location instead of UC or California-specific requirements.

6. IRB approval does not substitute for other approvals required by law or other university requirements.

7. Officials of the institution may not approve human subjects research that does not have IRB approval.
    i. UC San Diego interprets this regulatory requirement to mean that the institution may not allow the human subjects research portions of a project to proceed without IRB approval. However, other review bodies may issue approvals and other activities not involving human subjects may proceed, presuming that all required approvals applicable to those activities have been secured (e.g., IACUC approval for animal research).
    ii. Under exceptional circumstances and with the concurrence of the Vice Chancellor for ResearchVCR and Chancellor, the IO may direct a study disapprovedseek second consideration of an IRB's decision. Such consideration may be by the same IRB or by a second IRB, internal or external to UC San Diego by one IRB to a second IRB for review.
    ii. The.

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iii. second IRB must be informed that the study was initially disapproved and is be given pertinent information about the initial disapproval.

1. Consistent with federal guidance, if the decision was disapproval a second IRB must be informed of that disapproval and be given pertinent information about the initial disapproval.

iv.2. Exceptional circumstances may include, for example, 1) failure to reach timely determinations, 2) individual or institutional conflicts of interest, or 3) appeals by the IRB, the Director of OIA or the PI.

8. In reviewing non-compliance or other problems in a human subjects research project, an IRB Chair, IRB Director, or designee ("the Compliance Reviewer"):
   i. Shall:
      1. Conduct a preliminary aAssessment of the report of alleged noncompliance or problem in a timely fashion (e.g.,generally no later thanwithin 30 days of receipt). Preliminary assessment may be performed by a designated reviewer (eg, an IRB Chair, the Director or Medical Director of OIA, or other qualified IRB member designated by the above). All evaluations performed by the IRB should be completed within 90 days of initial assessment; the IO may provide one of more time extensions on a case-by-case basis.
      1.2. Determine whether immediate or long-term measures are necessary to stop or prevent harm to current or future subjects, including but not limited to temporarily suspending protocols or research human research privileges. A designated reviewer conducting a preliminary assessment may only take such actions to stop or prevent immediate harm.
      2.3. Determine whether to require modifications to research protocols.
      3.4. Determine whether to require notification to current or past human research subjects.
      4.5. Determine whether to suspend or terminate approval of the research project.
      6. Notify other institutional offices as applicable (for example, where a report suggests research misconduct).
      5.7. Complete its review of the matter in a timely fashion, generally within 90 days subject to factors such as complexity, cooperativeness of individuals involved, active evaluation by another unit, or other just cause.
   ii. May:
      1. Request that anotherother independent unit perform an audit, review, or investigationone the matter depending on the nature of the proposed action, such as Campus Counsel, Office of Ethics & Compliance, Health System Office of Compliance and Privacy, Audit and Management Advisory Services, or Office of Research Compliance and Integrity).
      1.2. Impose measures the IRB deems reasonably necessary to protect human research subjects in other any UC San Diego study where a nexus exists between the study and the alleged noncompliance or other problemies, for example where the same personnel, facilities, or investigational products are involved.
      2.3. Recommend disciplinary or other actions related to the academic or research mission (such as publication retractions or limitations on data use) and ask the Director of OIA to provide the recommendation actions (such as restrictions on data, publication, or privileges) to the IO or other University officials related to the academic mission, such as publication; however the IRB Compliance ReviewerIRB has no authority to require or impose such actions itself.

f) Protection from Undue Influence

1. Attempts to unduly influence UC San Diego IRBs or OIA staff constitute a serious violation of this Policy and may result in discipline.

1. The Director of the OIA shall develop a procedure for handling reports and shall normally be the initial point of contact for such reports, except as specified belowthat :
   Rreports about the actions of the Director of the OIA should instead go to the IO.

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~~ii.~~2. When reports are about a senior institutional official, the Director of OIA shall refer reports to that officer's supervisor (for example, the Chancellor for a report about a Vice Chancellor).

~~iii. When the Vice Chancellor for Research is not also the IO, reports about the actions of the IO should instead go to the Vice Chancellor for Research.~~

~~Reports about the actions of the Vice Chancellor for Research should instead go to the Chancellor or Chief Ethics & Compliance Officer.~~

~~iv. Reports about the actions of the Chancellor or Chief Ethics & Compliance Officer should go to the President of the University of California.~~

g) Policies, Guidance and Operating Procedures:

1. Effective on the issuance date of this policy, ~~as of dissemination of a draft of the 2020 version of this policythis document for campus community comment,~~ all extant policy statements published or cited by the IRBs or OIA are considered guidance instead of policy.
   i. These include but are not limited to "Standard Operating Policies & Procedures (SOPPs)," "FAQs" and "Fact Sheets."
   ii. ~~As guidance, those statements are not binding, however, this change~~This policy does not change, expand or reduce the applicability of regulatory requirements, advice of counsel, and University policies mentioned or referred to in those statements.
   iii. This ~~change~~ policy does not limit properly exercised IRB authority to require safeguards reasonably necessary for a given project.

2. The OIA is charged with establishing a process for proper and regular revision of guidance and operational procedures on a recurring basis of no less than once per five years. This process shall include requirements for:
   i. Stakeholder consultation
   ii. Approval of the IO, with any necessary consultation with the VCR and/or the Chancellor.

RESPONSIBILITIES

a) Institutional Official

1. Sign and uphold the Federalwide Assurance and any other required assurances.

2. Provide adequate resources and space for the IRBs and their staff to carry out duties.

~~Appoint and remove IRB members consistent with any applicable UC San Diego procedures. Designate Chairs and Vice Chairs. Set performance expectations and terms of reasonable duration.~~

3. Member terms shall be no more than ~~four~~~~three~~five years at a time, with renewal only by mutual agreement of the IO and the member.

~~3.~~

~~5.~~4. Regularly evaluate expertise needs and performance of the IRBs and their members and adjust membership accordingly.

~~6.~~5. Enter into agreements for external IRBs to review Human Subjects Research on behalf of UC San Diego; or for UC San Diego IRBs to review Human Subjects Research on behalf of other institutions, seeking advice from the Office of Campus Counsel and other campus officials as needed, as may be the case when agreements require novel indemnity or institutional liability terms.

~~7.~~6. Serve as approval authority for IRB Guidance and Operating Procedures under this Policy.

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7. Establish procedures to promptly and fairly resolve questions, complaints, or reports related to noncompliance with this Policy, noncompliance with IRB requirements, or threats to the rights and safety of human research subjects.
    i. IO has the authority and responsibility to make, or to delegate the making of, regulatory determinations such as "unanticipated problem involving risk to subjects or others," "serious non-compliance" and/or "continuing non-compliance.".
    ~~8.~~ii. Operational details of any such delegation, whether to an IRB or to another entity, shall be consistent with applicable UC or UC San Diego policies or procedures.

~~9.~~8. Make reports to oversight agencies as required by regulation. When the ~~Vice Chancellor for Research~~VCR is not also IO, the IO shall notify the ~~Vice Chancellor for Research~~VCR of all such reports as well as those reports from OIA that do not need to be forwarded to oversight agencies.

~~10.~~9. Take actions pertaining to IRB approved studies to protect human research subjects, including but not limited to suspensions of studies and/or ~~investigator privileges~~research activities. When the VCR is not also IO, the IO shall notify and discuss such actions with the VCR.

~~11.~~10. Refer to the appropriate Vice Chancellor, Dean, Chair, Chief, ~~or~~ Director or Unit Head any matters of discipline related to non-compliance with this policy or Code of Conduct and recommend appropriate remedial actions.

~~12.~~11. Protect regulatory independence of the IRB and respond to reports of undue influence upon the IRB or the OIA.

~~13.~~12. Establish and publish standards for training in human research protections, consulting and coordinating with relevant parts of the HRPP.

~~14.~~13. When the ~~Vice Chancellor for Research~~VCR is not also IO, the IO shall ~~notify~~ consult with the ~~Vice Chancellor for Research~~VCR of matters that involve significant institutional risk, impact on academic appointments, or inquiries from outside entities or agencies about ~~inquiries related to~~ possible non-compliance ~~from outside entities or agencies~~.

b) Institutional Review Boards

1. Receive submissions and perform timely, collegial reviews of human subject protections in a risk-proportionate manner and in accordance with criteria established by regulation and policy.

2. Exercise only those authorities established by regulation, this policy, or otherwise explicitly granted by the Institutional Official.

3. Exercise authority in a manner that promotes respect for the Boards' advice and counsel; the IRBs shall follow all applicable regulations and this Policy in their performance and operations, and the IRBs shall not create new policies or practices without appropriate delegated authority.

c) IRB Chairs and Vice Chairs (UC San Diego-operated IRBs only)

1. Meet at least once per year to:
    i. Ddiscuss issues and operational challenges of common interest
    ii. Mmaintain an appropriate consistency across boards
    iii. Fformulate policy recommendations to IO.

2. Manage regular and ad hoc IRB meetings.

3. Perform expedited reviews and designate additional expedited reviewers.

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4. Collaborate with Director of, OIA to provide the IO with feedback about performance of IRB members.

d) Researchers (and any Staff, Students, or other individuals working under their direction)

1. Protect human subject safety, rights, and welfare as per University requirements and the ethical standards of their discipline.
ii.1. PIs are responsible for human subject safety, rights, and welfare at all times, even if they delegate performance of tasks to others.

1. Identify when their activities engage UC San Diego in human subjects research and
iv.2. sSeek out formal determination from the OIA when unclear.

2.3. Obtain prospective review and either UC San Diego IRB approval or UC San Diego certification of exemption before:
   i. Conducting new UC San Diego human subjects research;
   ii. Implementing any changes to UC San Diego IRB-approved research (except where necessary to avoid immediate hazard to subjects);
   iii. Implementing any changes to exempt research that could affect exempt status; or
   iv. Continuing a project beyond its approval period (if applicable).

3.4. Obtain permission of the IO or designee when seeking to either rely on the IRB review of another institution or extend a UC San Diego IRB's review to cover activities at another institution.

4.5. Obtain approvals from committees, offices, or entities other than the IRB, as required by applicable policy, law or regulations.

5.6. Maintain control of and accountability for test articles used in clinical investigations except when another authorized entity (e.g., Pharmacy) has accepted such responsibility.

6.7. Conduct the research according to the approved protocol, the requirements of the IRB and other review entities, and applicable laws, policies, and regulations.

7.8. Delegate responsibility for tasks only to qualified individuals and ensure adequate training and supervision of those individuals.

8.9. Obtain and document informed consent as required.
   i. Notify subjects of new information that may be relevant to their safety, rights, or willingness to continue participation.
   ii. Consider consent an ongoing process.

9.10. Continuously evaluate and manage problems and deviations.
   i. Report as required to the IRB and/or other entities.
   ii. Respond promptly to questions, concerns or complaints from subjects.
   iii. Promptly take remedial action in the event of non-compliance with established protocols or any other act or omission that unduly threatens the health or welfare of human research subjects.

10.11. Report completion of non-exempt human subjects research to the IRB.

11.12. Maintain documentation sufficient to establish compliance with this policy and all directions from the IRB and OIA and maintain all other records required by University policy, and regulatory and contractual requirements.

e) Department Chairs/Unit Heads

1. Provide oversight of research conducted by study personnel in their departments or units.

2. Verify or confirm eligibility and sufficient resources to conduct research.

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3. Permit use of facilities, personnel, or resources only with appropriate approvals and in accordance with University policy and practice and the ethical standards of their discipline.

4. Facilitate and value IRB service by members of their departments or units.

5. Supervise and discipline researchers, as appropriate, for noncompliance or non-performance.

f) Office of IRB Administration

1. Develop forms, templates, and guidance and make those materials easily accessible so that researchers are able to:
   i. Uunderstand whether this Policy applies to their activities
   ii. Uunderstand and carry out their responsibilities
   iii. Pprovide clear and timely information needed for effective IRB review
   iv. Ccross-reference information already collected elsewhere
   v. Rreceive information about new requirements related to human research subjects protection.

2. Establish, maintain, and document procedures and systems by which submissions are received and routed in a timely fashion and tracked appropriately.

3. ~~Protect~~ Enhance the effective use of IRB member time and effort by implementing procedures to:
   i. Assign appropriate level of review
   ii. Screen for incomplete submissions and conduct pre-review
   iii. Conduct administrative and expedited reviews
   iv. Keep IRB reviews within proper authority
   v. Refer matters outside IRB jurisdiction to appropriate offices or processes.

4. Produce professional, clear and prompt communication on behalf of the IRBs.

5. Maintain documentation according to University and regulatory requirements.

6. Contribute to training, education, and communication about human subject protection.

7. Coordinate with other review processes involved in protection of human subjects.

8. Serve as a contact for questions, concerns, or suggestions from subjects.

PROCEDURES

N/A

FORMS

N/A

RELATED INFORMATION

[Placeholder for link to updated Systemwide Policy]

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Federal Register. 44 (76): 23191–7 (April 1, 1979).

Code of Federal Regulations, Title 45 (Department of Health & Human Services), Part 46

Code of Federal Regulations, Title 21 (Food & Drug Administration), Parts 50, 56, 312 and 812

California Health and Safety Code: Human Experimentation (Sections 24170-24179.5)

Contracts & Grants Manual Chapter 18, University of California Office of the President

Terms of Federalwide Assurance

FREQUENTLY ASKED QUESTIONS (FAQs)

N/A

REVISION HISTORY

xx/xx/2021~~0~~- Previous version rescinded and completely rewritten and reformatted.

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DEFINITIONS

Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the FDA under these sections of the FDCA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Common Rule: The Federal Policy for the Protection of Human Subjects as adopted into regulation by multiple federal agencies, including the Department of Health and Human Services (DHHS), National Science Foundation (NSF) and Department of Defense (DOD). For ease when citing specific provisions of the Common Rule, this policy and related policy, guidance, or procedure documents will generally refer to DHHS regulations at Title 45, Part 46, Subpart A of the Code of Federal Regulations (45 CFR 46).

Engagement: Generally, when UC San Diego is the prime awardee of funding for Human Subjects Research or when individuals exercise UC San Diego-granted authority or responsibility or perform UC San Diego-designated activities for human subjects research or obtain informed consent for human subjects research.

Exempt: Activities that constitute human subjects research but do not require IRB review because they have been administratively certified as 1) fitting into one or more exempt categories in applicable regulations, 2) not otherwise limited by regulation or policy, AND 3) meeting UC San Diego ethical standards as set out by OIA.

Human Research Protection Program: Those entities referred to by the Scope section of this policy (not to be confused with the former name of the OIA).

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens. For FDA-regulated research, “human subject” includes an individual (or their specimens in the case of device research) who is either the recipient of a test article or a control, whether patient or healthy individual.

Human Subjects Research: An activity that is either (a) “research” as defined below AND involves one or more “human subjects” as defined above or (b) a “clinical investigation” as defined above. “Clinical investigations” for treatment purposes (without research aims) are not considered “human subjects research” but this policy is applicable to the extent required by FDA regulations.

Institutional Official (IO): The official to whom the Chancellor delegates authority to sign assurances of, and to oversee the University’s responsibility for, the protection of human subjects.

Institutional Review Board (IRB): A board established in accordance with and for the purposes expressed in the Common Rule and FDA regulations. For the purposes of this policy, a UC San Diego IRB is any IRB:

- operated by UC San Diego and designated under UC San Diego’s Federalwide Assurance; or,
- operated by another institution but reviewing on behalf of the University with the agreement of the Institutional Official (or designee).

Principal Investigator (PI): The person working on behalf of UC San Diego who is responsible for the ethical conduct of the research and for carrying out the responsibilities described in this policy. Generally, in order to serve in this capacity for human subject protections an individual must be eligible under UC San Diego policy to submit proposals for extramural support and serve as PI. The protocol PI (for human subject protection purposes) does not have to be the same person as the award PI (for funding purposes).

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Undue influence: The deliberate use of improper means (such as intimidation, deception, bribery or exploitation of a vulnerability) to attempt or achieve improper ends (such as getting IRB staff or members to disregard legal responsibilities or institutional policy). Influence is not undue if it consists only of 1) persuading, disagreeing or criticizing, 2) using proper channels to change, or seek exceptions from, requirements or processes, or 3) disclosing, preventing or correcting improper or inefficient exercise of IRB authority.

POLICY STATEMENT

a) Overall Policy

1. UC San Diego and its employees share responsibility for protecting human subjects according to the requirements of applicable regulations and University policies.

2. University of California policy applies the Common Rule or commensurate protections to all human subjects research in which UC San Diego is engaged.

3. This policy on Protection of Human Research Subjects applies to all human subjects research in which UC San Diego is engaged, regardless of funding source, funding status, or the location or scale of the Research.

4. Additional regulations or policies may apply. In case of conflict between applicable regulations, the more restrictive regulations prevail.

b) Commensurate Protections

1. Consistent with University of California systemwide policy, IO has the authority to approve alternatives to specific Common Rule requirements for research that is not otherwise subject to the Common Rule (for example, provisions relating to the Federal government's role as a funder of research may be impossible to follow for unfunded research). The OIA has the responsibility to ensure that such alternatives provide commensurate protection to subjects and do not conflict with other applicable regulations. OIA will be responsible to maintain written documentation of the rationale and the approved alternative requirements.

2. For situations in which FDA regulations require IRB review of treatment and there are no research aims associated with such treatment (e.g., expanded access to investigational products; devices that may be marketed under Humanitarian Use Device status), the IRB will use a modified process consistent with prevailing FDA guidance for efficiency while ensuring regulatory requirements are met. OIA will be responsible to maintain written documentation of the rationale and the approved modified process(es).

c) Jurisdiction of the Human Research Protection Program

1. The UC San Diego HRPP covers all UC San Diego engagement in human subjects research.
    i. The HRPP does not normally cover human subjects research in which UC San Diego is not engaged. In rare cases, the IO may agree to extend the UC San Diego HRPP to cover unaffiliated individual investigators collaborating with UC San Diego. Such an arrangement requires a formal agreement and the active involvement of the UC San Diego PI and approval by the VCR.
    ii. If another institution or unaffiliated research investigator relies on UC San Diego IRB review services, a documented arrangement is required. Unless explicitly agreed, UC San Diego is not responsible for on-site monitoring or conduct of the research by another institution or unaffiliated investigators relying on UC San Diego IRB review services.

2. Researchers might determine that their activities do not constitute human subjects research or do not engage UC San Diego, or researchers may request such a determination by OIA. Only OIA may provide official determinations on behalf of UC San Diego.

i. The IO may also delegate such authority to other units, subject to appropriate training, documentation and audit standards (e.g., Health System QA/QI program). IO shall periodically assess delegation and may revoke or limit any such delegation.
ii. Consistent with requirements of this policy, OIA shall provide guidance and tools so that decisions made by OIA or others are based on regulatory and University criteria and are made efficiently.

d) Certification of Exemption from IRB Review

1. When UC San Diego is engaged in human subjects research, only individuals authorized under this Policy and not otherwise associated with the project may certify a project as exempt from IRB review.
    i. UC San Diego uses all permissible exemption categories.
    ii. The IO may authorize creation of additional exemption categories for use with projects that are eligible for commensurate protections.
    iii. Any additional exemption categories shall be consistent with the nature and risk of the categories used in regulations.

2. Certification of exemption relates only to UC San Diego IRB review. Researchers (and individuals working on their behalf) may not express or imply that a certification exempts research from other applicable legal or institutional requirements.

3. IO and Director of OIA are each authorized to:
    i. Certify projects as exempt from IRB review.
    ii. Accept another institution's exemption certification as sufficient for UC San Diego.
    iii. Permit the use of a validated self-certification tool.
    iv. Delegate the above authorities to appropriate units, contingent upon ongoing compliance with training, documentation and audit standards.
    v. Limit or revoke delegations of the above authorities for serious and/or continuing failure to comply with training, documentation and audit standards.

e) IRB Authority

1. For all proposed human subjects research in which UC San Diego is engaged that is not otherwise exempt from IRB review, a UC San Diego IRB has authority to:
    i. Approve or disapprove.
    ii. Require modifications in order to secure IRB approval.
    iii. Suspend or terminate its approval.
    iv. Observe (or have a third party observe) the consent process or the research.
    v. Grant waivers related to informed consent.
    vi. Grant waivers related to authorization under the Health Insurance Portability and Accountability Act (HIPAA).
    vii. Review eligible research via the expedited process described in 45 CFR 46.110 and 21 CFR 56.110.

2. Consistent with the *Responsibilities* section of this Policy, IO may delegate additional authorities to the IRB (for example, authority to make determinations of "serious non-compliance").

3. UC San Diego IRBs shall exercise the above authorities only in accordance with criteria established by federal or state regulation for human subject protections, the advice of campus authorities, University of California policy, and/or properly promulgated UC San Diego policy.
    i. When presented with matters outside their scope of authority, the IRBs shall ask the Director of OIA to refer such matters to other appropriate offices.
    ii. The Director of OIA and IRB Chairs will seek advice of University Counsel, the IO and/or the Vice Chancellor for Research (VCR) as needed.

4. To maintain high standards while providing effective and efficient service to researchers, UC San Diego IRBs make use of flexibility offered by regulations and policies. Examples include,

but are not limited to, expedited review for minimal risk research or waivers related to consent.

i. UC San Diego IRBs shall generally offer or grant flexibilities when appropriate for eligible studies even if a PI does not request such flexibilities. Some examples of this include, but are not limited to:
    1. Regardless of level of review requested by the Principal Investigator, the expedited review process may be used if the study is eligible.
    2. If a study is eligible for a waiver of signed informed consent but the study team fails to request this explicitly, the IRB may grant a waiver of signed informed consent, as appropriate.

ii. UC San Diego IRBs retain the authority to make protocol-specific determinations that flexibility would not provide adequate subject protection.
    1. Such determinations must be documented, including protocol-specific justifications for the determinations.
    2. When such determinations are discussed at convened IRB meetings, the Chair shall call a specific vote. In order for the proposal to pass, a majority of the quorum must approve the proposal.

5. When reviewing on behalf of another institution, a UC San Diego IRB:
    i. May exercise additional authorities explicitly granted by that institution in its policies and/or in the reliance agreement.
    ii. May be prohibited from exercising authorities e(1)v-vii and e(2) above.
    iii. Shall apply local requirements of that institution and/or the research location instead of UC or California-specific requirements.

6. IRB approval does not substitute for other approvals required by law or other university requirements.

7. Officials of the institution may not approve human subjects research that does not have IRB approval.
    i. UC San Diego interprets this regulatory requirement to mean that the institution may not allow the human subjects research portions of a project to proceed without IRB approval. However, other review bodies may issue approvals and other activities not involving human subjects may proceed, presuming that all required approvals applicable to those activities have been secured (e.g., IACUC approval for animal research).
    ii. Under exceptional circumstances and with the concurrence of the VCR, the IO may seek second consideration of an IRB's decision. Such consideration may be by the same IRB or by a second IRB, internal or external to UC San Diego.
        1. Consistent with federal guidance, if the decision was disapproval a second IRB must be informed of that disapproval and be given pertinent information about the initial disapproval.
        2. Exceptional circumstances may include, for example, 1) failure to reach timely determinations, 2) individual or institutional conflicts of interest, or 3) appeals by the IRB, the Director of OIA or the PI.

8. In reviewing non-compliance or other problems in a human subjects research project, an IRB:
    i. Shall:
        1. Conduct a preliminary assessment of the report in a timely fashion (generally within 30 days of receipt). Preliminary assessment may be performed by a designated reviewer (eg, an IRB Chair, the Director or Medical Director of OIA, or other qualified IRB member designated by the above).
        2. Determine whether immediate or long-term measures are necessary to stop or prevent harm to current or future subjects, including but not limited to temporarily suspending protocols. A designated reviewer conducting a preliminary assessment may only take such actions to stop or prevent immediate harm.
        3. Determine whether to require modifications to research protocols.
        4. Determine whether to require notification to current or past human research subjects.

5. Determine whether to suspend or terminate approval of the research project.
6. Notify other institutional offices as applicable (for example, where a report suggests research misconduct).
7. Complete its review of the matter in a timely fashion, generally within 90 days subject to factors such as complexity, cooperativeness of individuals involved, active evaluation by another unit, or other just cause.

ii. May:

1. Request that an independent unit audit, review, or investigate the matter.
2. Impose measures the IRB deems reasonably necessary to protect human research subjects in any UC San Diego study where a nexus exists between the study and the alleged noncompliance or other problem, for example where the same personnel, facilities, or investigational products are involved.
3. Recommend disciplinary or other actions related to the academic or research mission (such as publication retractions or limitations on data use) and ask the Director of OIA to provide the recommendation to the IO or other University officials; however the IRB has no authority to require or impose such actions .

f) Protection from Undue Influence

1. Attempts to unduly influence UC San Diego IRBs or OIA staff constitute a serious violation of this Policy and may result in discipline.

2. The Director of OIA shall develop a procedure for handling reports and shall normally be the initial point of contact for such reports, except that reports about the actions of the Director of OIA should instead go to the IO. When reports are about a senior institutional official, the Director of OIA shall refer reports to that officer's supervisor (for example, the Chancellor for a report about a Vice Chancellor).

g) Policies, Guidance and Operating Procedures:

1. Effective on the issuance date of this policy, all extant policy statements published or cited by the IRBs or OIA are considered guidance instead of policy.
   i. These include but are not limited to "Standard Operating Policies & Procedures (SOPPs)," "FAQs" and "Fact Sheets."
   ii. This policy does not change, expand or reduce the applicability of regulatory requirements, advice of counsel, and University policies mentioned or referred to in those statements.
   iii. This policy does not limit properly exercised IRB authority to require safeguards reasonably necessary for a given project.

2. The OIA is charged with establishing a process for proper and regular revision of guidance and operational procedures on a recurring basis of no less than once per five years. This process shall include requirements for:
   i. Stakeholder consultation
   ii. Approval of the IO, with any necessary consultation with the VCR and/or the Chancellor.

RESPONSIBILITIES

a) Institutional Official

1. Sign and uphold the Federalwide Assurance and any other required assurances.

2. Provide adequate resources and space for the IRBs and their staff to carry out duties.

3. Appoint and remove IRB members consistent with any applicable UC San Diego procedures. Designate Chairs and Vice Chairs. Set performance expectations and terms of reasonable

duration. Member terms shall be no more than four years at a time, with renewal only by mutual agreement of the IO and the member.

4. Regularly evaluate expertise needs and performance of the IRBs and their members and adjust membership accordingly.

5. Enter into agreements for external IRBs to review Human Subjects Research on behalf of UC San Diego; or for UC San Diego IRBs to review Human Subjects Research on behalf of other institutions, seeking advice from the Office of Campus Counsel and other campus officials as needed, as may be the case when agreements require novel indemnity or institutional liability terms.

6. Serve as approval authority for IRB Guidance and Operating Procedures under this Policy.

7. Establish procedures to promptly and fairly resolve questions, complaints, or reports related to noncompliance with this Policy, noncompliance with IRB requirements, or threats to the rights and safety of human research subjects.
    i. IO has the authority and responsibility to make, or to delegate the making of, regulatory determinations such as “unanticipated problem involving risk to subjects or others,” “serious non-compliance” and/or “continuing non-compliance”.
    ii. Operational details of any such delegation, whether to an IRB or to another entity, shall be consistent with applicable UC or UC San Diego policies or procedures.

8. Make reports to oversight agencies as required by regulation. When the VCR is not also IO, the IO shall notify the VCR of all such reports as well as those reports from OIA that do not need to be forwarded to oversight agencies.

9. Take actions pertaining to IRB approved studies to protect human research subjects, including but not limited to suspensions of studies and/or research activities. When the VCR is not also IO, the IO shall notify and discuss such actions with the VCR.

10. Refer to the appropriate Vice Chancellor, Dean, Chair, Chief, Director or Unit Head any matters of discipline related to non-compliance with this policy or Code of Conduct and recommend appropriate remedial actions.

11. Protect regulatory independence of the IRB and respond to reports of undue influence upon the IRB or the OIA.

12. Establish and publish standards for training in human research protections, consulting and coordinating with relevant parts of the HRPP.

13. When the VCR is not also IO, the IO shall consult with the VCR of matters that involve significant institutional risk, impact on academic appointments, or inquiries from outside entities or agencies about possible non-compliance.

b) Institutional Review Boards

1. Receive submissions and perform timely, collegial reviews of human subject protections in a risk-proportionate manner and in accordance with criteria established by regulation and policy.

2. Exercise only those authorities established by regulation, this policy, or otherwise explicitly granted by the Institutional Official.

3. Exercise authority in a manner that promotes respect for the Boards’ advice and counsel; the IRBs shall follow all applicable regulations and this Policy in their performance and operations, and the IRBs shall not create new policies or practices without appropriate delegated authority.

c) IRB Chairs and Vice Chairs (UC San Diego-operated IRBs only)

1. Meet at least once per year to:
    i. Discuss issues and operational challenges of common interest
    ii. Maintain an appropriate consistency across boards
    iii. Formulate policy recommendations to IO.

2. Manage regular and ad hoc IRB meetings.

3. Perform expedited reviews and designate additional expedited reviewers.

4. Collaborate with Director of OIA to provide the IO with feedback about performance of IRB members.

d) Researchers (and any Staff, Students, or other individuals working under their direction)

1. Protect human subject safety, rights, and welfare as per University requirements and the ethical standards of their discipline. PIs are responsible for human subject safety, rights, and welfare at all times, even if they delegate performance of tasks to others.

2. Identify when their activities engage UC San Diego in human subjects research and seek formal determination from the OIA when unclear.

3. Obtain prospective review and either UC San Diego IRB approval or UC San Diego certification of exemption before:
    i. Conducting new UC San Diego human subjects research;
    ii. Implementing any changes to UC San Diego IRB-approved research (except where necessary to avoid immediate hazard to subjects);
    iii. Implementing any changes to exempt research that could affect exempt status; or
    iv. Continuing a project beyond its approval period (if applicable).

4. Obtain permission of the IO or designee when seeking to either rely on the IRB review of another institution or extend a UC San Diego IRB's review to cover activities at another institution.

5. Obtain approvals from committees, offices, or entities other than the IRB, as required by applicable policy, law or regulations.

6. Maintain control of and accountability for test articles used in clinical investigations except when another authorized entity (e.g., Pharmacy) has accepted such responsibility.

7. Conduct the research according to the approved protocol, the requirements of the IRB and other review entities, and applicable laws, policies, and regulations.

8. Delegate responsibility for tasks only to qualified individuals and ensure adequate training and supervision of those individuals.

9. Obtain and document informed consent as required.
    i. Notify subjects of new information that may be relevant to their safety, rights, or willingness to continue participation.
    ii. Consider consent an ongoing process.

10. Continuously evaluate and manage problems and deviations.
    i. Report as required to the IRB and/or other entities.
    ii. Respond promptly to questions, concerns or complaints from subjects.
    iii. Promptly take remedial action in the event of non-compliance with established protocols or any other act or omission that unduly threatens the health or welfare of human research subjects.

11. Report completion of non-exempt human subjects research to the IRB.

12. Maintain documentation sufficient to establish compliance with this policy and all directions from the IRB and OIA and maintain all other records required by University policy, and regulatory and contractual requirements.

e) Department Chairs/Unit Heads

1. Provide oversight of research conducted by study personnel in their departments or units.
2. Verify or confirm eligibility and sufficient resources to conduct research.
3. Permit use of facilities, personnel, or resources only with appropriate approvals and in accordance with University policy and practice and the ethical standards of their discipline.
4. Facilitate and value IRB service by members of their departments or units.
5. Supervise and discipline researchers, as appropriate, for noncompliance or non-performance.

f) Office of IRB Administration

1. Develop forms, templates, and guidance and make those materials easily accessible so that researchers are able to:
    i. Understand whether this Policy applies to their activities
    ii. Understand and carry out their responsibilities
    iii. Provide clear and timely information needed for effective IRB review
    iv. Cross-reference information already collected elsewhere
    v. Receive information about new requirements related to human research subjects protection.
2. Establish, maintain, and document procedures and systems by which submissions are received and routed in a timely fashion and tracked appropriately.
3. Enhance the effective use of IRB member time and effort by implementing procedures to:
    i. Assign appropriate level of review
    ii. Screen for incomplete submissions and conduct pre-review
    iii. Conduct administrative and expedited reviews
    iv. Keep IRB reviews within proper authority
    v. Refer matters outside IRB jurisdiction to appropriate offices or processes.
4. Produce professional, clear and prompt communication on behalf of the IRBs.
5. Maintain documentation according to University and regulatory requirements.
6. Contribute to training, education, and communication about human subject protection.
7. Coordinate with other review processes involved in protection of human subjects.
8. Serve as a contact for questions, concerns, or suggestions from subjects.

PROCEDURES

N/A

FORMS

N/A

RELATED INFORMATION

[Placeholder for link to updated Systemwide Policy]

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Federal Register. 44 (76): 23191–7 (April 1, 1979).

Code of Federal Regulations, Title 45 (Department of Health & Human Services), Part 46

Code of Federal Regulations, Title 21 (Food & Drug Administration), Parts 50, 56, 312 and 812

California Health and Safety Code: Human Experimentation (Sections 24170-24179.5)

Contracts & Grants Manual Chapter 18, University of California Office of the President

Terms of Federalwide Assurance

FREQUENTLY ASKED QUESTIONS (FAQs)

N/A

REVISION HISTORY

xx/xx/2021- Previous version rescinded and completely rewritten and reformatted.