The Office of IRB Administration

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• What is the UCSD Human Research Protections Program?
• What is the Office of IRB Administration?
  • What is an IRB?
  • What do we do?
  • How do you get in touch/work with us?
What is the UCSD Human Research Protections Program?

- PPM 100-5
Not Just the IRB

• 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)

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).
The Office of IRB Administration (OIA)

- IRB Administration became necessary due to the establishment of human subjects protections regulations in late last century based on the ethical principles of the Belmont Report.
  - Respect for Persons
  - Beneficence
  - Justice
- We are but one branch of the UCSD human research protections program.
OIA - What do we do?

We review and facilitate the review of human research in accordance with the requirements of federal regulation, state law, UCOP and UCSD policies.

- Expedited (In-office) review
- Exempt determinations
- NSHR determinations
- Reliance Agreements
Administrative Determinations

• Not Human Subjects Research
  • 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.

• Exemption
  • Only OIA may certify

• Reliance Agreements
  • Only OIA may enter into
Other types of reviews that are not research:

- Expanded access requests
- Requests for HUD use in accordance with HDE at our facility
Do you need OIA review?

**Is it Research?**

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

**Does it involve Human Subjects?**

- 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.
Do you need OIA review?

• Is it FDA-regulated?
  • Any experiment that involves a test article (drug, biologic, device) and one or more human subjects
  • 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.
An IRB is an Institutional Review Board. It is a group of people that review research proposals involving human subjects.

The Office of IRB Administration administers (manages/coordinates) the IRBs at UCSD. We have seven of them (6 biomedical, 1 social-behavioral).
Who makes up the people on the IRB?

- Scientists and Non-scientists
- Affiliated and unaffiliated with the institution
- Mix of genders
When can the IRB review?

There has to be a quorum (a minimum portion of all members on the roster) for the board to convene and for their reviews to “count.”

Adequate expertise must be available to review the research under consideration.
Regulatory Criteria for IRB Approval of Research

• Risks to subjects are minimized:
  • (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
  • (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

• Selection of subjects is equitable.
Regulatory Criteria for IRB Approval of Research

• Informed consent
  • will be sought or appropriately waived
  • will be appropriately documented or signature waived

• Data
  • When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
  • When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Regulatory Criteria for IRB Approval of Research

• All human research, regardless of category of review, must satisfy the regulatory criteria for approval.

• There may be additional requirements for IRB approval depending on factors like:
  • State law (e.g., research involving prisoners)
  • Funding (e.g., Department of Defense).

• Officials of the institution may not approve human subjects research that does not have IRB approval.

• IRB approval does not substitute for other approvals required by law or other university requirements.
Getting in Touch/Working With Us

• Kuali IRB: online submission and review portal
  • ucsd.kuali.co/protocols
  • Accessible from anywhere there is internet access
    • Use AD credentials
    • Must be faculty, staff, or have a sponsored account for access

• Knowledge Base Articles

• Training Videos
Getting in Touch/Working With Us

• Our website
  • Irb.ucsd.edu (new one going live very soon!)

• Service Now Ticketing system
  • Email irb@ucsd.edu for any IRB-related questions
  • Email irbrely@ucsd.edu for any IRB reliance-specific questions
  • support.ucsd.edu/research

• Leave a voicemail: 858-246-4777
Please complete the SURF Evaluation

We want to hear from you!