Office of IRB Administration | OIA

The UCSD Office of IRB Administration (OIA) exists to promote high quality, ethical research. The OIA does this by serving as the advocate for the rights and welfare of persons who participate in research programs conducted by UCSD faculty, staff, and students.

Though located within the School of Medicine, the OIA has responsibility for review of research involving human subjects conducted by all Schools, Centers and Programs of UCSD. The OIA assists researchers in complying with federal, state and University policies regarding experimentation involving human subjects, and oversees the review and conduct of research conducted by federally-registered *Institutional Review Boards* (IRBs).

Federal Wide Assurance | FWA

The program operates under Federalwide Assurance number, FWA00004495. A statement letter about the FWA is available here .

Institutional Review Boards | IRB

UCSD's HRPP supports six federally registered IRBs:

- **Biomedical IRBs:**
  - IRB00000353
  - IRB00000354
  - IRB00002758
  - IRB00005945 (specializes in pediatric projects)
  - IRB00009940 (specializes in oncology projects)
- **Social and Behavioral Sciences IRB:**
  - IRB00000355

The IORG number for UCSD is 0000210 (effective through March 3, 2020).

Last updated: 25 Apr 2022

Guidance & SOPPs

The current versions of the UCSD OIA Guidance & Standard Operating Policies and Procedures (SOPPs) have been "revised" to provide these policies and procedures separately rather than as one guideline.

Last updated: 25 Apr 2022

- Submit a new project application
- Submit a response to a letter from the IRB
- Amend an existing project
- Submit information for annual (or more frequent) Continuing Review by the IRB
- Submit a project renewal
- Submit a project withdrawal or closure
- More

How to...

- Submit a new Biomedical Project Application
- Submit a new SBS Project Application
- Submit a new RCHSD-only Project

  Studies conducted by RCHSD researchers that have no affiliation with UCSD and are requesting UCSD IRB oversight

- Submit a new exempt status study

  Studies that are minimal, minimal risk and that satisfy criteria for exemption from IRB review

- Submit a Response to a letter from the IRB
- Amend an existing project
- Submit information for Continuing Review
- Submit a "Resubmission" of an existing, approved project after 10 IRB reviews completed
- Submit a Study Withdrawal or Closure

Last updated: 7 Feb 2019

Submitted research activities may fall into one of the following four regulatory classifications:

- **Not “Human Research”**

Activities must meet the organizational definition of “Human Research” to fall under IRB oversight. Activities that do not meet this definition are not subject to IRB oversight or review. Review the IRB Box Chart or Flow Chart for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.

- **Exempt**

Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the organization, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Administration’s Exemption Fact Sheet for reference on the categories of research that may be 'Exempt'.

- **Expedited**

Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the IRB Administration’s SOPP regarding Expedited Review for reference on the categories of research that may be reviewed using the expedited procedure.

- **Convened IRB | Full Board**

Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB (Full Board)

Last updated: 25 Mar 2019

Criteria for IRB Approval

In order to evaluate and potentially approve human subjects research, the UC San Diego IRB must review the protocol and determine that all of the federal requirements for approval - as outlined in 45 CFR 46.111(a)(1-7)(b) - are satisfied. The criteria for IRB approval can be found here.

? **Research cannot commence until fully approved by the IRB.**

? **IRB approval occurs when the HRPP releases an approval letter containing the approval date.**

Categories of IRB Action

After reviewing a research proposal, the IRB has the authority to take one of the actions outlined below. Except when the expedited review process is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with IRB's conflict of interest policies.

- **Approved**

Made when all criteria for approval are met. See "*Criteria for IRB Approval*" above.

- **Approved Pending**

Made when IRB members require specific modifications to the research before approval can be finalized.

- **Deferred**

Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.

- **Disapproval**

Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

Last updated: 18 Dec 2018

See the Topics section of the HRPP website.

Last updated: 25 Mar 2019

See HRPP Training resources

Last updated: 25 Mar 2019

Access e-IRB Services here.

Last updated: 25 Mar 2019

How to Submit information for Continuing Review

Federal Regulation required that projects undergo Continuing Review at intervals not greater than 365 days. Courtesy reminders regarding upcoming expiration dates may be sent electronically at intervals set by users of the HRPP

system. The default reminders are sent 75, 60 and 45 days before a project expires, but these intervals, and the entire reminder service, can be set to a user's preference using our e-IRB services . However, this courtesy notification should not substitute for the researcher's own internal tracking of expiration dates. Ultimately, it is the PI's responsibility to submit documentation within the due dates provided. Items should be uploaded to the HRPP **not less than 45 days before expiration of the current IRB approval!**

A Continuing Review submission has three or more components:

- A cover letter for submission of Continuing Review documents
- Continuing Review Facepages. There are two different Facepages, one for a Biomedical project and one for a SBS project . The Facepages must be signed by the PI and submitted to HRPP at mailcode 0052, if provided as a hardcopy document, or uploaded as a .PDF file through eIRB services.
- A Continuing Review Narrative Summary of Progress made since the most recent IRB review. There are two different Narrative Summary forms, one for a Biomedical project and one for a SBS project .
- A copy of the IRB-stamped, approved blank consent/assent form currently in use by the project. (Note: although HRPP has a copy of this on file, federal regulations require that you send us the current consent/assent so that the IRB can determine that you are using the correct version.) ***Do not send a consent/assent that has been signed by a study participant.***
- A "clean" copy of the consent/assent form, as a Word document, for "restamping."
- Associated study documentation, including a copy of any site monitoring reports, progress reports, audits, communication to/from the FDA, and/or publications associated with the project, as applicable, since the most recent IRB review.

Step-by-step directions for submitting Continuing Review for a **Biomedical Research** project with visual aids

Step-by-step directions for submitting Continuing Review for a **Social and Behavioral Science** project with visual aids

Last updated: 25 Mar 2019

Last updated: 25 Apr 2022

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