

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 2.3
Orientation and Training

Policy

Training of Investigators, IRB members and IRB staff, and research personnel conducting research involving human subjects will meet the requirements set forth in the most recent version of the PHS *Policy on Instruction In The Responsible Conduct Of Research*. The IRB will provide training for its members and staff. The institution will provide or recommend a program of instruction for investigators and research staff to comply with this policy and will document its adherence to the provisions of this policy.

Training for IRB members

Prior to attending his/her first IRB meeting as a member, all regular and alternate members will receive, at a minimum, access to or copies of the following:

1. UCSD HRPP Standard SOPPs
2. UCSD IRB fact sheets on selected topics
3. FDA Information Sheets and Guidelines when issued
4. 45 CFR 46 (DHHS: Protection of Human Subjects)
5. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects
6. 21 CFR 50 (FDA: Protection of Human Subjects)
7. 21 CFR 56 (FDA: Institutional Review Boards)
8. 21 CFR 812 (FDA: Investigational Device Exemptions)
9. 21 CFR 312 (Investigational New Drug Application)
10. OHRP Reports and Guidelines
11. Other materials as appropriate

All IRB members will complete the appropriate Collaborative Institutional Training Initiative (CITI) online training module(s) (at <http://www.citiprogram.org>) prior to starting as active members, and this will be documented. Prior to attending their first meeting as a voting member, a new IRB member should meet with the Chair or designee to discuss specific responsibilities and duties and familiarize him or herself with the IRB meeting format and sign the "UCSD Human Research Protections Program Confidentiality and Computer Security Agreement." Institutional Review Board members are also encouraged to attend external meetings where regulatory issues are discussed in order to be knowledgeable about current issues. At the introduction of new/revised SOPP, all IRB members and staff will be provided with a training session on the revised components, normally as part of a scheduled IRB meeting.

Training for Investigators and Research Personnel

Investigators and research personnel must comply with all external research training requirements of sponsoring organization (e.g., key personnel training requirements of NIH-funded research).

The UCSD HRPP program website contains links to classroom training opportunities and also a links to online human research protections training maintained by CITI with input from the UCSD HRPP. Additional training may also be required by the IRB in response to noncompliance identified during review or during audits.

The HRPP Office will also provide individuals, upon request, with ready access to copies the Belmont Report and all relevant federal, state, and institutional regulations via its website (<https://irb.ucsd.edu>) and also paper copies on request.

Ongoing Educational Programs

The HRPP Office has an ongoing educational program for both IRB members and investigators. Particular emphasis of training is placed on vulnerable populations including those with cognitive disabilities, children and prisoners. Examples of educational opportunities that are offered are as follows:

1. Courses through Staff Education and Development. Classes include the application process, informed consent, adverse event reporting, amendment requirements and other processes.
2. In-service educational presentations that are regularly scheduled components of convened IRB meetings.
3. Classes tailored and presented for specific research units or investigators such as the departments of surgery or psychiatry.
4. An on-line web tutorial for all investigators and IRB members that meets NIH training guidelines.
5. Educational programs for undergraduate students.
6. Educational sessions for Institute of the Americas graduate students
7. Educational sessions for UCSD medical students engaged in research as a component of their Independent Study Project (ISP).
8. Educational presentations to Pharmacy Fellows.

Procedures

1. IRB Administrator establishes new IRB member and staff orientation in the following:
 - a) Regulations and Guidance: Drug (21 CFR 312) and Medical Device (21 CFR 812) FDA regulations; other FDA regulations (21 CFR 54); Protection of Human Subjects (21 CFR 50 and 56, 45 CFR 46); ICH guidelines; other guidelines (Belmont Report, Declaration of Helsinki, etc.); and applicable FDA and OHRP guidance documents.
 - b) Policies, Procedures and Operations: review of forms (IRB, FDA); site reviews and reports; expedited reviews; reviewing adverse event reports; reviewing recruitment materials/advertisements; scheduling meetings; conducting reviews, including new and continuing reviews; support staff

responsibilities; access to written resources; and confidentiality requirements.

- c) New staff training in the following: use of office computer systems; management of electronically submitted applications and reviews (“e-IRB”); paper files and archiving; interactions with Sponsors and Investigators; applications for New and Continuing Review; and Initial review of project-related correspondence.
- d) Conduct and document education of new members and staff and periodic continuing education of existing members and staff and maintain access to relevant regulatory and clinical reference materials.

Applicable Regulations

[21 CFR 56.107 \(a\)](#)

[45 CFR 46.107 \(a\)](#)

[Policy on Instruction In The Responsible Conduct Of Research](#)

References, Forms, and Links

Training links of UCSD HRPP program website: <https://irb.ucsd.edu>