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Mission

In partnership with the research community, the UCSF HRPP is responsible for ensuring the ethical and equitable treatment of all human research subjects in studies being conducted at UCSF and its affiliates and partners and/or being conducted by UCSF faculty, regardless of site of activity. The HRPP is also responsible for ensuring compliance with federal regulations, state laws and institutional polices, as well as national standards.

Mission of the HRPP

The mission of the HRPP is

- to promote the welfare and rights of human research participants,
- to facilitate excellence in human research, and
- to provide timely and high quality education, review and monitoring for human research projects.

To safeguard the rights and welfare of human research subjects, UCSF adheres unequivocally to the principles of The Belmont Report, as described in detail below.

Ensuring human research participants are protected

Human research protection is a collaborative, ongoing enterprise involving multiple groups at UCSF: high-level administrators, the pharmacy staff, researchers and their staff, the HRPP staff, IRB chairs and members, sponsors and funding agencies, the Office of Sponsored Projects, hospital and campus risk management, legal counsel, staff who provide support services provided to researchers, research institutes, and the research participants themselves. These groups work closely together to ensure the ethical, safe and legal conduct of the research enterprise.

The HRPP offers outreach and education, including the required online human subjects training [1] for research key personnel, IRB members and HRPP staff. Researchers are asked to fill out complex applications, which are then carefully screened by HRPP staff and reviewed by the IRB, in order to ensure awareness of and compliance with regulations.

Primarily through the QIU, [2] the HRPP performs post-approval monitoring, including screening of post-approval events and on-site monitoring of the conduct of research. Other units at UCSF that also monitor research conduct include, but are not limited to, the Comprehensive Cancer Center, the Clinical and Translational Sciences Institute and its Clinical Research Centers, and the SF VAMC Clinical Research Office. Research sponsors and cooperative groups also monitor compliance on a regular basis, and their findings are communicated to the HRPP.

Particular goals of the education and monitoring include ensuring that

- All key personnel engaged in human research have sufficient training in their ethical and regulatory responsibilities,
- No research activities begin until all required approvals are in place, and
- Researchers do not implement changes in a human research study without first obtaining approval for the amendments from the IRB.

Taken as a whole, the educational efforts and monitoring seek to increase awareness of ethical issues and promote a culture of regulatory compliance in human research at UCSF and associated institutions.

The HRPP has gone through formal quality improvement processes that have resulted in reorganizations to increase its efficiency and effectiveness. The HRPP also frequently discusses and coordinates program improvements with its primary constituents and collaborators at UCSF.

Organization

The UCSF HRPP is located administratively within the O [3]ffice of Research [4]. The Institutional Official overseeing the HRPP is the Associate Vice Chancellor, [4]Research Infrastructure & Operations [4]. Both the HRPP Policy Group and the IRB Panels operate

under the leadership of the Associate Vice Chancellor. Below is more information on the roles and responsibilities of these groups.

University Administration

University Administration is responsible for the rights and welfare of human research participants. UCSF through the Office of the Executive Vice Chancellor assures the federal government that the campus is in compliance with federal regulations regarding the protection of human subjects in research and that no research involving human subjects is conducted without prior review and approval.

UCSF grants the IRB the authority to function independently of other organizational entities in its role in protecting research participants.

UCSF provides adequate resources to support the activities of the HRPP, which includes the IRB and the Quality Improvement Unit.

UCSF may provide treatment and compensation for injured research subjects [5].

The University provides legal protection for members of the IRB and to principal investigators granted approval to conduct such research who have met their obligations in good faith.

University Administration is responsible for assuring that investigations occur for individual incidents or allegations of misconduct pertaining to the use of humans in research. To report incidents of non-compliance or unauthorized research, call the IRB at 415-476-1814. For a more detailed description of this process, please read Reporting Research-Related Concerns and Complaints [6].

The University provides whistle-blowing protection for anyone who reports an activity that violates any regulations and policies on the use of human subjects.

Under the provisions of the federal Freedom of Information Act and California's Public Records Act, the University is required, upon request, to release to the public documentation on any active or retired protocol.

HRPP Policy Group

The HRPP Policy Group serves as an advisory group to the Associate Vice Chancellor. It is a standing committee composed of the Chairs and Vice-Chairs of each of the IRB panels, the Institutional Official, the Associate Vice Chancellor for Research, the HRPP Director and Associate Directors, UCSF Legal Counsel, the Deputy Associate Chief of Staff for Clinical Research at the VA, a member of the Research Advisory Board, a representative of the Clinical and Translational Research Institute and other members as appointed by the Associate Vice Chancellor. If one of the members previously mentioned is not a member of the Cancer Center, then a representative from the Cancer Center will also be appointed. Others may be invited to or request to attend the meeting to provide additional expertise or perspectives.

The group meets several times a year to review, revise and develop UCSF policies for the

protection of human subjects and human research at UCSF. Before policies are finalized and promulgated, they are reviewed and approved by UCSF Legal Counsel with input from UC General Counsel as needed.

Institutional Review Board

Operating under federal regulations, state laws and institutional policies, the IRB research involving human subjects [7] to ensure the ethical and equitable treatment of those subjects. At present, the IRB is composed of four panels [8] that share equal authority and responsibility. No University official can overrule a disapproval by a IRB panel, although others in the institution may decide that a study that is approved by the IRB should not go forward.

See the About the IRB [9] page for more information on the roles and responsibilities of the IRB.

HRPP Units

The Director of the HRPP reports to the Associate Vice Chancellor and is responsible for the daily functioning and overall planning and development of the HRPP. The units of the HRPP are described below:

- The ***IRB Review*** [9] [10] ***Unit*** [9] supports the activities of the IRB panels in a variety of ways. They coordinate the committee reviews by setting the agendas, assigning reviewers to the studies, providing regulatory and policy support and guidance during the review process, and preparing follow up communication for the investigators after the meeting.
- The ***Quality Improvement Unit*** (QIU) [2] provides post-approval support for researchers by assessing and helping to manage post approval events and by conducting on-site reviews of studies. In addition, the QIU is responsible for conducting directed investigations. The unit is also involved with the quality assurance and improvement of the HRPP itself. The QIU also handles education and training.

Federal Regulations, State Statutes, Institutional Policies and Guidance

The UCSF HRPP adheres to Campus Administrative Policies 100-16: Research Involving Humans [11], as well as UCSF Medical Center Policies 6.07.11 [12] regarding patient participation in research protocols. The UCSF HRPP also operates according to the University of California [13] policies and guidelines pertaining to research. Because the IRB reviews studies being conducted at the San Francisco Veterans Affairs Medical Center, it ensures that its policies and procedures are in alignment with those at the SF VAMC [14].

As appropriate for particular studies depending on funding source and agency jurisdiction, the HRPP applies the following basic legal principles:

- Federal Policy for Protection of Human Subjects: Common Rule (45 CFR 46).
- Food and Drug Administration Regulations (Title 21): Protection of Human Subjects (21 CFR Part 50); Institutional Review Boards (21 CFR Part 56); Investigational Device Exemptions (21 CFR Part 812); Investigational Device Exemptions for Intraocular Lenses (21 CFR Part 813); Investigational New Drug Application (21 CFR Part 312).

- Office of Civil Rights Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164)
- Department of Veterans Affairs regulations 38 CFR 17 and VHA Handbook 1200.5
- Applicable California law
- University of California Policy on the Protection of Human Subjects in Research, policies 18-200, and 18-210 through 18-240.
- Any other applicable federal, state or local regulations.

See the Federal Regulations, State Statutes and Guidance page [15] for more information.

Program Feedback

We welcome your concerns, complaints, suggestions or compliments about our performance. You may provide feedback to us by contacting us [16] directly. If you wish, you may provide feedback to us ***anonymously*** by not including your name when you call or write the HRPP.

You may also provide direct feedback to the Associate Vice Chancellor ? Research Infrastructure & Operations (AVC ? RIO) [4], who is also the Institutional Official overseeing the HRPP.

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Links
[1] http://irb.ucsf.edu/citi-human-subjects-training
[2] http://irb.ucsf.edu/monitoring
[3] http://compliance.ucsf.edu/
[4] https://research.ucsf.edu/
[5] http://irb.ucsf.edu/treatment-and-compensation-injury
[6] http://irb.ucsf.edu/reporting-research-concerns-and-complaints
[7] http://irb.ucsf.edu/research-needing-irb-review
[8] http://irb.ucsf.edu/irb-rosters-meeting-dates
[9] http://irb.ucsf.edu/irb-review
[10] http://irb.ucsf.edu/events/post-approval-event-reporting
[11] http://policies.ucsf.edu/policy/100-16
[12] http://manuals.ucsfmedicalcenter.org/AdminManual/IndividualPolicies/PatientParticipationinResearchProtocols.PDF
[13] http://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/index.html
[14] http://irb.ucsf.edu/research-sfvamc
[15] http://irb.ucsf.edu/regulations-statutes-guidance
[16] https://hrpp.ucsf.edu/contact-us