Purpose

To safeguard the rights and welfare of human subjects of research, the University of California, San Francisco (UCSF) ascribes unequivocally to the principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* [3] by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. UCSF has established policies to assure full compliance with all federal regulations, state laws, and University of California policies governing the use of human subjects in research.

Policy

A. Federal Policy on the Protection of Human Subjects

1. Any institution that receives funds from and is accountable to departments and agencies of the federal government for funds awarded for the support of research using human subjects is required to safeguard the rights and welfare of those subjects.

2. No federal grant or contract for research involving human subjects may be made to any institution unless the application for such support has been reviewed and approved by the appropriate IRB. (See Section III.B).

3. The FDA restricts data used in support of market permits to that from IRB-approved studies.

4. The use of any drug not approved by the FDA in humans is subject to review and approval by an IRB. The sole exception to this requirement is in the case of certain treatment investigational new drugs.

5. Reviews by an IRB must determine that subjects will be adequately protected according to established criteria involving an evaluation of risks and benefits, equity of selection, and the informed consent process and documentation.

6. Approved studies must be reviewed at least annually by an IRB. Modifications to a study must be approved before they are implemented.

B. UCSF Policy on the Protection of Human Subjects in Research

1. Guiding Principles
The principles espoused in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* have been adopted by UCSF and the HRPP for all research involving human subjects.

2. Scope of Authority

UCSF holds a Federalwide Assurance of Compliance with DHHS regulations (FWA #00000068) for the protection of human subjects (45 Code of Federal Regulations 46). This assurance, which is regularly renegotiated and approved, applies to all federally-funded research with human subjects (as defined in 45 CFR 46.102[3] and [f]) being conducted by investigators acting as agents of UCSF regardless of the site of the activity. The Assurance applies to all human research involving any UCSF facilities, personnel, patients, or students or research that is supported either by federal funds granted to, or applied for through, The Regents of the University of California, or for research conducted with federal funding at non-UCSF sites.

Commensurate protections are in place for all other human research conducted at or under the jurisdiction of UCSF. UCSF also assures compliance with FDA regulations (21 CFR parts 50, 56, 312 and 812), applicable state laws, and University of California and UCSF policies for the protection of human subjects in research.

a. The CHR has sole authority to grant IRB approval for human research applications.

b. If the CHR does not grant IRB approval or suspends or terminates IRB approval, these decisions may not be overturned at any higher level.

c. Implementation of CHR-approved studies may be prevented or terminated by decision at any other level in the institution, although the CHR approval shall not be voided by such action.

3. Jurisdiction

All faculty and staff paid by UCSF for greater than 50% of their effort who are conducting studies involving human subjects within the course and scope of their duties, regardless of the source of the funding, or even in certain cases in which no funds are involved, are required without exception to have prior approval from the CHR before research is initiated.

Regardless of percent of effort, prior approval of the CHR is required, without exception, when studies conducted by UCSF faculty access any UCSF or UCSF-affiliated facilities, patients, personnel, or students and/or when the human research is supported either by extramural funds granted to, or applied for through, The Regents of the University of California, or for research conducted with UCSF funding at non-UCSF sites.

Prior approval of the CHR is not required when part-time or unpaid faculty are not acting as staff members, employees, or agents of the University, when no University facilities, patients, personnel or students are used and when the activity is not represented to subjects as being conducted under the aegis of the University. However, in such cases investigators holding University appointments nevertheless are required to obtain approval for the use of human subjects from a duly constituted IRB.
4. Activities Accessing UCSF Facilities, Patients, Staff, or Students Not Being Conducted by a UCSF Principal Investigator

All non-UCSF investigators involving human subjects in research projects that access any UCSF facilities, patients, staff or students must either identify a UCSF faculty member to serve as the Principal Investigator for the project or submit the research proposal to the CHR for administrative review. This CHR review will determine the following:

a. Whether the study must have a UCSF faculty member serve as the Principal Investigator, or

b. Whether the study can be certified as exempt, and/or

c. Whether the study will require an additional review and approval by the Office of the Associate Vice Chancellor for Research.

5. Treatment and Compensation for Injured Research Subjects

The University policy on treatment and compensation for injured research subjects must appear on all consent forms for studies in which there is a more than minimal risk of biomedical harm.

6. Experimental Subject's Bill of Rights

Any individual who is asked to consent to participate as a subject in a medical experiment or who is asked to consent on behalf of another must be given a copy of the UCSF Experimental Subject's Bill of Rights in a language in which the person is fluent or in Braille if the participant is visually impaired.

Responsibilities

A. Executive Vice Chancellor and Provost

1. The Executive Vice Chancellor and Provost is responsible for implementation of and compliance with federal regulations, state laws, and University policy;

2. The Executive Vice Chancellor and Provost appoints the CHR chairs and members after consultation with appropriate constituencies;

3. The Executive Vice Chancellor and Provost has delegated the daily operation of the Research Involving Human Subjects program to the Associate Vice Chancellor for Research.

B. Committee on Human Research

1. The CHR is obligated and authorized to:

a. Ensure that subjects are adequately informed of the nature of the study;

b. Ensure that subjects' participation is voluntary;

c. Ensure that the benefits of a study outweigh its risks;

d. Ensure that the risks and benefits of the study are evenly distributed among the possible
subject populations; and

e. Require necessary modifications of study applications to secure approval;

f. Observe, or have a third party observe, the consent process and/or the conduct of research.

g. Suspend or terminate any human research activity that violates regulations, policies, procedures, or an approved protocol, and report such violations, suspensions or terminations to the Executive Vice Chancellor and Provost, other appropriate parties within the institution and appropriate federal agencies.

2. The CHR is responsible for conducting timely review of all applications for the use of human subjects.

3. The CHR notifies investigators and appropriate UCSF officials in writing of its decision to approve or withhold approval of applications or modifications of ongoing activities.

4. The CHR develops policies and procedures in consultation with the Executive Vice Chancellor and Provost as appropriate.

5. The CHR refers legal issues to the UCSF Office of Legal Affairs, which may seek the advice of the UC General Counsel.

6. The CHR directs and reviews investigations of concerns about issues of human subject protection and directs corrective action as needed.

C. The Quality Improvement Unit (QIU)

1. The QIU is authorized to conduct on-site reviews and investigations of human research activities on behalf of the CHR.

2. The QIU is involved in assessing and processing post-approval event reports, including but not limited to reports of adverse events, protocol violations or incidents, safety reports, and concerns and complaints.

3. The QIU refers any reports of unanticipated problems involving risks to study participants or others as well as incidents or allegations of serious and or continuing noncompliance to the CHR for review and management.

4. The QIU responds to PI requests for the emergency use of an investigational drug or device.

5. The QIU refers legal issues to the UCSF Office of Legal Affairs which may seek the advice of the UC General Counsel.

D. Principal Investigators

1. The principal investigator must submit an application to the CHR for review and approval before initiating, modifying, or extending any research project using human subjects.

2. The principal investigator shall consider racial, cultural, and gender diversity among the
subject populations and be sensitive to community attitudes in both the design and conduct of research involving humans.

3. The principal investigator must report to the CHR any serious or unexpected adverse event on-site related to research participation experienced by a subject within 10 working days of having become aware of the event. The principal investigator also must report any problems or incidents related to the conduct of a study or patient participation, including those in the recruitment or consent process.

4. The principal investigator shall report to the CHR any violation of an experimental protocol or any use of subjects not approved by the CHR.

E. Department Chair

The department chair is responsible for reviewing the activities within the department to determine that

1. Proper review and approval have been obtained.
2. Appropriate resources are available to conduct the research.
3. Scientific or scholarly review for human research studies is available if needed.

F. University

1. The University of California assures the federal government that the campus is in compliance with federal regulations as described in Section III.B.2 above for the use of human subject research and that no research involving human subjects is conducted without prior review and approval.
2. The University of California may provide treatment and compensation for injured research subjects.
3. The University of California is legally responsible for the acts and omissions of its employees acting in the course and scope of their University duties. In the event of a suit against an employee in connection with a CHR-approved research activity using human subjects, the University assumes the employee's defense and indemnification.

Related Policies

- 100-24 - Biosafety [4]
- 100-22 - Radioactive Drug Research [5]
- 100-23 - Radiation Safety [6]

References

- UCSF Campus Code of Conduct [7]
- Code of Federal Regulations [10]: Food and Drugs (Title 21): Protection of Human Subjects (21 CFR Part 50); Institutional

- Federalwide Assurance of Compliance with DHHS, Committee on Human Research
- UCSF Human Subjects Protection Website [12]
- UCSF Office of Research Website [13]
- G-39, Conflict of Interest Policy and Compendium of Specialized University Policies Guidelines, and Regulations related to Conflict of Interest [14]