Published on *UCSF Institutional Review Board* (http://irb.ucsf.edu)



# IRB Review

The IRB must review all research that involves human subjects [1] performed by UCSF faculty, staff, or students or researchers at UCSF-affiliated institutions [2] before the research can begin. Four committees [3] share the responsibilities of the IRB. The IRB review process [4] and review times [5] varies depending on the level of review [6] required.

If you are collaborating with an outside institution [7], that site typically will need its own IRB approval before work can begin there. In limited circumstances, UCSF investigators can rely on another IRB [8] to review their research.

What is the IRB?

An IRB is a committee ? operating under federal regulations, state laws and institutional policy ? that reviews research involving human subjects to ensure the ethical and equitable treatment of those subjects. The IRB:

- Reviews all human subject research [1] at UCSF and affiliate sites [2].
- Has the authority to approve, require changes in or disapprove research involving human subjects.
- Includes representatives from the institutions whose research is reviewed. Members ? such as physicians, nurses, pharmacists, social scientists, and at least one non-affiliated member and one non-scientist ? are qualified to review the range of research at the institutions. The Associate Vice Chancellor for Ethics and Compliance appoints IRB chairs and members [3].
- Has final authority to disapprove human-subject research at the institutions. No institutional official may overrule IRB disapproval, but institutions may choose not to support or permit research that the IRB has approved.

- Operates in compliance with relevant federal regulations, state laws and institutional policies and with a signed agreement between the institutions and the Department of Health and Human Services, called a Federalwide Assurance (FWA) [9].
- May be audited by the Food and Drug Administration, the Department of Health and Human Service's Office for Human Research Protections and Office of Civil Rights, cooperative research groups, and UCSF Internal Audit, among others.
- Serves as the Privacy Board [10] for research at UCSF.

Charge of the IRB

It is the duty of the IRB to review and make decisions on all protocols for research involving human subjects. Its primary responsibility is the protection of subjects from undue risk and from deprivation of personal rights and dignity.This protection is best assured by consideration of three principles which are the touchstones of ethical research:

- that voluntary participation by the subjects, indicated by free and informed consent, is assured;
- that an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- that there be fair procedures and outcomes in the selection of research subjects.

These principles are summarized as *respect for persons, beneficence*, and *justice* in " The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research [11]" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979).

At times, these issues are quite clear; other times, they are extremely difficult to evaluate. Researchers themselves should begin the process by examining their own projects in light of these principles as they prepare to seek IRB approval. The IRB then brings its collective experience in reviewing each study, always conscious of its primary responsibility to protect the rights of human subjects against exploitation, but within the context of the need for continued scientific and human progress.

*Respect for Persons*: The Voluntary Participation of Experimental Subjects

One of the most important elements in any research involving human subjects is assurance of free and informed consent. Any person who is to be a subject of research, whether designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the potential risks and benefits are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB attempts to ensure free and informed consent of subjects through careful review of the recruitment and consent process, and of the consent form or information sheet to be used with subjects.

The informed consent concept is extended to those studies in which subjects are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the subject's well-being (e.g., parents for children). The

Committee's concern is to verify that the consent process and document are likely to assist these persons to make an informed decision which is in the best interests of the subject.

The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme there may be ample understanding and manifest freedom from coercion; at the other, total absence of capacity for personal consent. In between, there are many degrees of understanding and freedom that affect the consent of potential subjects. The IRB must exercise special care when considering subjects whose ability to give free and informed consent may be compromised in any way.

*Beneficence:*The Risk-Benefit Ratio

The IRB is charged with deciding, for any proposed activity which falls under its jurisdiction, whether: "The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks " (*Federal Register*, May 30, 1974).

The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the Committee must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.

While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any subject at risk, however minimal. Thus, the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the Committee.

*Justice*: The Fair Selection of Research Subjects

Both the risks and the potential benefits of research should be spread fairly among potential individual subjects and subject groups. Study design and selection of subjects should avoid bias for or against particular social, racial, sexual, or ethnic groups.

*Sharing Research Risks*: The guiding principle in the ethical selection of subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other care) simply because they are easily accessible or can be persuaded to participate. Groups already burdened by other factors should not also be burdened by an undue share of research risks. Rather, attempts should be made to include a fair sampling of the populations who might benefit from a study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of

the subject population.

In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations. Investigational drugs usually are tested in adults before they are tested in children. Certain investigational drugs and procedures may be tested in healthy volunteers before being tested in patients.

*Sharing Research Benefits*: In recent years increasing attention has been paid to the rights of various groups to be included in research. As individuals and through advocacy groups, many patients have come to insist on having access to experimental treatments as these experimental treatments may potentially provide the best medical care available. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focussed primarily on white male middle-class subject groups, the results of some trials were of questionable value for members of other social, racial, sexual, and ethnic groups. As a result, both the Food and Drug Administration and the National Institutes of Health now require that study design include as broad a range of subjects as feasible and ask that data be analyzed to uncover responses that differ between groups. Where women of child-bearing potential and pregnant or nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

While in the past participation in research was viewed as a burden, it is now often seen as a right. Many in society now believe that only by participating in research can an individual or a group of subjects expect to experience the benefits of the advances being made in the biomedical and behavioral fields of research. This is a major shift in public perception of medical research.

## Scope

The IRB reviews research projects that involves human subjects performed by UCSF faculty, staff or students or researchers at UCSF-affiliated institutions, as described on the Research Requiring IRB Review page [1]. This page also defines criteria for when an activity is research involving human participants.

The vast majority of the human research projects at UCSF are related to the health sciences, but the IRB reviews a broad range of research within that area. The human research participants in the studies include a wide range of individuals from all walks of life and from all over the world. The HRPP attempts to ensure that special protections are provided for participants who are vulnerable for any reason or economically disadvantaged.

## History of the IRB

Since 1966, the United States Department of Health and Human Services (DHHS), formerly called the Department of Health, Education and Welfare (DHEW), has required prior review and approval of all research using human subjects that is funded by federal agencies. In 1970, the President of the University of California required that U.S. Public Health Service Regulations apply to "all investigations involving human subjects for which the University is

responsible." This policy was re-stated in 1981.

DHEW issued its "Institutional Guide to DHEW Policy on Protection of Human Subjects" in December of 1971. Subsequently, the University of California made the DHEW policy applicable to all human subject activities conducted by or under the direction of University employees, regardless of the source of funding or even when no funds are involved. DHEW guidelines were revised and made regulation in 1974.

Between 1974 and 1978, the National Commission on Protection of Human Subjects of Biomedical and Behavioral Research met and issued a series of reports and recommendations resulting in revised regulations issued by DHHS in January of 1981. The United States Food and Drug Administration (FDA) was simultaneously developing its own regulations, which were also issued in January of 1981 and have since been revised, most recently in October 1996. DHHS issued revised regulations in March of 1983 and again in June of 1991. These regulations, which provided standards for review of human research activities by institutional review boards now apply to all activities involving human subjects within the University.

The IRB was first created in 1966 and then restructured in 1971, both times with one panel. The second panel was created in 1997, the third in 2002, and the fourth in 2005. Each panel meets twice a month. The QIU was established in late 2002 to help improve and assure the quality of human research at UCSF. This unit in conjunction with the IRB are the two units that now comprise UCSF?s Human Research Protection Program.

The campus holds an approved Federalwide Assurance (FWA) [9] from DHHS. This is a written agreement in which UCSF describes the jurisdiction, composition, and methods of procedure by which the IRB will function, and the in the DHHS approves it.

At the start of 2015, there were 5700 IRB-approved studies, up from 3500 studies in 2003. The federal government supports 38% of the total number of human research studies at UCSF and provides 78% of the total funding for UCSF?s human research. However, industry-sponsored studies are increasing both in numbers and the amount of money awarded. There are about four biomedical studies to every one behavioral study reviewed.

## Responsibilities of the IRB

It is the responsibility of the IRB to safeguard the rights and welfare of human subjects. To this end, the Committee is obligated and authorized to systematically evaluate each research study to ensure the protection of participants, including but not limited to the following:

- Identify and analyze potential sources of risk and measures to minimize risk, including physical, psychological, social, legal or economic
- Determine that the risks to participants are reasonable in relation to potential benefits to participants and to society
- Review plans for data and safety monitoring in research protocols and, when applicable, determine that the plan provides adequate protection for the participants
- Determine risks for vulnerable populations as defined in federal regulations and determine the specific risk categories in protocols involving children and prisoners
- Establish and follow written procedures for suspending or terminating previously approved research if warranted by findings in the continuing review or monitoring

process
- Evaluate the equitable selection of participants
- Review and permit when appropriate proposed participant recruitment methods, advertising materials, and participant payment arrangements
- Evaluate the protection of privacy interests of research participants and confidentiality of data in proposed research
- Evaluate compliance with policies and procedures for seeking informed consent from participants or their legally authorized representatives, and assent from participants when appropriate
- Require that prospective participants whose decision-making capacity is in question be appropriately protected
- Review the consent process and the consent documents, focusing on measures to improve participant understanding and voluntary decision making
- Require that the investigator has and follows a procedure for properly documenting informed consent
- Review and approve the waiver or alteration of the consent process and the waive of consent documentation when appropriate
- Review protocols that request exceptions to the informed consent requirements for emergency situations and approve as appropriate
- Have procedures for observation of the informed consent process
- Have procedures for the review and oversight of research conducted at multiple sites
- Maintain documentation of its activities
- Make the applications, forms, guidelines and policies necessary for the proper conduct of human research publicly available to the research community on the HRPP website
- Serve as the IRB of record for UCSF and affiliate institutions [2]

**Page last updated:**
Jan 11, 2016





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**Links**
[1] http://irb.ucsf.edu/node/307
[2] http://irb.ucsf.edu/node/586
[3] http://irb.ucsf.edu/node/531
[4] http://irb.ucsf.edu/node/327
[5] http://irb.ucsf.edu/node/317
[6] http://irb.ucsf.edu/node/386
[7] http://irb.ucsf.edu/node/886
[8] http://irb.ucsf.edu/node/312
[9] http://irb.ucsf.edu/node/891
[10] http://irb.ucsf.edu/node/302
[11] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html