Does My Research Require IRB Review?

Research Involving Human Subjects

The IRB must review all research that involves human subjects performed by UCSF faculty, staff or students or researchers at UCSF-affiliated institutions, as described below.

What is the definition of*research*?

DHHS Regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge according to 45 CFR 46.102[1] Common Rule.

For purposes of IRB review, we further defines the following terms:

A ?systematic investigation? as an activity involving a prospective plan that incorporates:

- the organized collection of quantitative and/or qualitative data, or biological specimens, and
- analysis (or anticipation of analysis) of those data or specimens to answer a question or questions.

?Generalizable knowledge? is information based on results or findings that are expected:

- to be reproducible, and
- applied broadly with the expectation of predictable outcomes

The following activities are deemed **not** to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individual(s) about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

FDA Regulations defines clinical investigation as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA n under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).

What is the definition of a *human subject*?

DHHS Regulations define human subject as a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e)(1).

We further define the following:

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between an investigator and a subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information (see above) for which the identity of the subject is or may readily be determined by the investigator or linked (directly or indirectly) with the information.

An *identifiable biospecimen* is a biospecimen is a biospecimen for which the identity of the subject is or may readily be determined by the investigator or is (directly or indirectly) with the biospecimen.

See the Not Human Subjects Research [1] guidance if your research involves only unidentifiable/de-identified or coded private information or biospecimens.

FDA Regulations define a human subject as an individual who becomes a participant in research, either as a recipient of the test article (drug, device or biologic) or as a control. *(21 CFR 50.3(g), 21 CFR 56.103(e), 21 CFR 312.3(b), and 21 CFR 812.3(p))*

- A subject may be either a healthy individual or a patient.
- If the research involves a medical device, individuals are considered ?subjects? when they participate in an investigation, either as an individual on whom an investigational device is used or as a control. Further, individuals are considered "subjects" when they participate in an investigation, in which their specimen(s) is used or as a control.

Note: Under limited circumstances, research involving only unidentifiable or coded private information or specimens is not human subjects research [1]. Also review the Quality Improvement (QI) and Quality Assurance guidance [2], as well as the Quick Guide: Activities Needing IRB Approval [3], to learn more about what activities need IRB review and approval.

Who Needs IRB Approval

UCSF faculty, staff, or students or researchers at UCSF-affiliated institutions [4] conducting human subjects research require IRB approval before initiating the study. IRB approval is required regardless of the site of the study or the source of funding (if there is funding).

Requirements for UCSF faculty and staff researchers

UCSF-affiliated researchers involving human subjects must receive prior approval from the IRB if any of the following circumstances apply:

Researchers Paid > 50% Time by UCSF

All faculty and staff paid by UCSF for greater than 50% of their effort must have IRB approval before they begin research involving human subjects. This requirement applies regardless of the source of funding and even when no funds are involved, and regardless of the site of the study activities.

Researchers Paid < 50% Time by UCSF

If researchers are paid by UCSF for less than 50% of their effort, they need not obtain IRB approval for human research, unless one of the following conditions applies:

- The funding is granted to or applied for through UCSF, or
- Subjects will be recruited at UCSF, ZSFG (formerly SFGH) or the SFVAMC, or
- The research will take place at a UCSF, ZSFG or SFVAMC facility.
- A UCSF-affiliated institution holds an FWA that identifies the UCSF IRB as the IRB of record for all its human research.

Per UCSF PI eligibility requirements or the PI eligibility requirements of the various affiliates: If the above conditions apply, researchers must arrange for an eligible faculty member to serve as the PI for the study, or they may obtain a waiver from the Department Chair. This is because researchers paid less than 50% time are not typically eligible to serve as PI at UCSF nor are they eligible to have research reviewed by the IRB.

Important Note: Even if IRB review is not required, any investigator holding a UCSF appointment must obtain approval from another IRB before conducting human research. Anyone accepting the privilege of a UCSF faculty title must also assume the duty of obtaining prior approval from a duly-constituted IRB in order to conduct human research.

Funding awarded through UCSF

If the human research is supported either by extramural funds granted to (or applied for through) the Regents of the University of California or by University funds, IRB review is required.

If UCSF is the primary recipient of a grant, then the UCSF PI must obtain IRB approval, even if the research is being conducted elsewhere only for the scope of work. If multiple sites are involved, the IRB will require evidence of the various and relevant IRB approvals at all subcontracted sites.

If UCSF has been awarded a subcontract and is not the prime recipient of the grant, then the IRB need review only the subcontracted portion of the study that will be completed by the UCSF researcher.

See the FAQ below about Just in Time review.

Post docs, clinical fellows, residents and students

Postdoctoral fellows, clinical fellows and residents are allowed to serve as PIs on IRB applications if certain conditions are met.

Students are **not eligible** to serve as PIs, as described below.

Students who are doing research at sites that are not affiliated with UCSF may not need individual approval from the UCSF IRB if:

- their mentor (PI) is not a UCSF faculty member;
- they already have an IRB approval from the other institution;
- they are not supported by extramural funds granted to (or applied for through) the Regents of the University of California or by University funds; and
- they are not accessing UCSF facilities, medical records, patients or personnel.

If they are accessing any of these, they will need individual UCSF IRB approval with a qualified UCSF faculty member to serve as the PI.

Researchers from other UCSF-affiliated institutions for which the UCSF IRB is the institution's IRB

Several institutions have signed agreements and Federalwide Assurances designating the UCSF IRB as the institution?s IRB [4] (e.g., SFGH, SFDPH, SFVAMC, Gladstone Institutes, Gallo Institutes). Researchers working under the auspices of those institutions must obtain IRB approval for human research as required by individual institutional policies, and are eligible to obtain IRB review as determined by UCSF institutional policies.

IMPORTANT NOTE: Investigators who wish to use facilities, involve patients or employees, or recruit subjects from any UCSF-affiliated institution must contact each institution to see what if any their additional requirements are. For example, the SF VAMC has its own set of requirements [5].

Research not being conducted by a UCSF PI but accessing UCSF facilities, patients or personnel

All human subjects research conducted at UCSF facilities or involving UCSF patients or employees (including students, faculty and staff) must either identify a UCSF faculty member.

Research conducted by UCSF Emeritus Professors

Emeritus Professors may ask that the UCSF IRB review their studies, provided any funding is brought through UCSF, if there is funding.

Principal Investigator (PI) and Co-PI Eligibility

The PI must be a UCSF faculty member who meets the eligibility requirements for PI status on grant applications [6]. The PI is ultimately responsible for all aspects of conducting the research study [7].

For studies conducted under the auspices of an affiliated institution [4] (e.g., SFVAMC, UCSF-Fresno, etc.), the PI must meet eligibility criteria defined by that institution.

PI status request

If you are not eligible for PI status based on your appointment [6], you must be approved for PI status to submit an application to the IRB. Attach a signed PI Status Waiver Form [8] to your IRB Application.

Special requirements for postdoctoral fellows, clinical fellows and residents

Postdoctoral fellows, clinical fellows and residents are now allowed to serve as PIs on IRB applications if the following two conditions are met:

- A UCSF faculty member who would otherwise qualify as a PI is identified as the Co-PI on the application, and
- A cover letter from the Co-PI faculty member is attached to the application stating that he or she agrees to serve as faculty support and/or a mentor to the fellow or resident listed as PI in the IRB Application.

Students cannot be PIs

Students cannot serve as PIs. They are required to seek the sponsorship of a UCSF faculty member, who will serve as the PI on the study. These studies are often smaller scale unfunded studies.

Co-Principal Investigator (Co-PI) eligibility requirements

The Co-PI must be faculty, staff or student at UCSF or one of the institutions that have signed agreements designating UCSF as its IRB. The Co-PI must be prepared to assume some of the responsibilities of the PI when the PI is unavailable and, thus, cannot be at an unaffiliated institution.

FAQs

Does stem cell research need review?

Yes. Further guidance can be found at the GESCR - Human Stem Cell Research website [9].

What about research on decedents and/or data death files?

The health information of deceased individuals is protected under federal and state regulations. IRB review is determined by the level of Protected Health Information (PHI) [10]

associated with the data.

- **Records With No PHI:** If the decedent study will not have direct access to PHI, IRB review and approval is **not required** because the deceased individuals cannot be identified.
- **Records With PHI:** Decedent research that will have direct access to medical records or PHI, even if identifiers will not be recorded, must be submitted for IRB review and approval.

Death Data Files: California law [11] requires local IRBs to review research using State of California-produced death data files that contain personal identifying information (i.e., state issued death certificates and indices). Submit an application to the IRB. The law specifies that the research can be approved only if the researcher has a "valid scientific interest" in the information. You may also need to obtain approvals from the CA Department of Public Health Vital Statistics Advisory Committee [12] and the CA Health and Human Services Agency's Committee for the Protection of Human Subjects [13].

IRB Review Level Required for Decedent Research

Access to or Use of Medical Records	Use of PHI from State, County, Local Death Data Files	Level of IRB Review	IRB Consent and HIPAA Authorization Requirements
No	No	None	None
No	Yes	Expedited*	IRB Waiver of Consent and Authorization
Yes	Either Yes or No	Expedited*	IRB Waiver of Consent and Authorization

* Expedited review is required unless other parts of the study require full committee review.

What if I have NIH Just In Time (JIT) review?

To ensure that your JIT IRB application is handled expeditiously, email the UCSF IRB Expedited and Exempt Coordinator Manager (Joanne.Mickalian@ucsf.edu [14]) with JIT in the subject line as soon as NIH issues a JIT notice. In the e-mail text, provide the study number, summarize the JIT request including the due date, and indicate whether this is a single site protocol (i.e., data collection solely at UCSF sites) or whether UCSF is also serving as a coordinating center or data center for a study that includes two or more data collection sites.

When preparing your iRIS submission, fill out item 1.9 of the Initial Review Submission Packet noting ?NIH JIT? and the due date.

Does a pilot study need IRB review?

Yes. It isn't the number of subjects that determines if review is needed; the determining factor is whether or not human subjects are involved. Make sure the aims of study are clear in the Purpose and Background section of the protocol.

Does research on samples from cadavers require IRB review?

IRB review is not needed if the materials do not contain personal identifiers (PHI) [15]. However, if personal identifying information is linked to the materials, then expedited review is required.

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Links
[1] https://irb.ucsf.edu/not-human-subjects-research
[2] https://irb.ucsf.edu/quality-improvement-qi-and-quality-assurance-qa
[3] https://irb.ucsf.edu/quick-guide-activities-requiring-irb-review
[4] https://irb.ucsf.edu/ucsf-affiliated-institutions
[5] https://irb.ucsf.edu/research-sfvamc
[6] http://osr.ucsf.edu/content/pi-status
[7] https://irb.ucsf.edu/responsibilities-pis-and-crcs
[8] https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/pi%20status%20waiver%20form%202019.pdf
[9] https://irb.ucsf.edu/stem-cell
[10] https://irb.ucsf.edu/definitions
[11] http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=102001-103000&file=102175-102249
[12] https://www.cdph.ca.gov/services/boards/Pages/VSAC.aspx
[13] http://www.oshpd.ca.gov/Boards/CPHS/index.html
[14] mailto:Joanne.Mickalian@ucsf.edu
[15] https://irb.ucsf.edu/hipaa