



University of California  
San Francisco

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## When UCSF Can Serve as IRB of Record

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### UCSF as IRB of Record

The UCSF IRB serves as the IRB for UCSF and many UCSF-affiliated organizations [1]. UCSF also has Reliance Agreements with the following entities in for which the UCSF IRB can be the IRB of record:

- University of California - Memorandum of Understanding (MOU) Between Human Research Protection Programs [2]
- Children's Hospital & Research Center Oakland (CHRCO) [2]

In general, the UCSF IRB cannot be considered the IRB of record for non-affiliated institutions or investigators, but there are a few exceptions described below.

See the [Relying on Other IRBs \[2\]](#) page for information on the responsibilities of the reviewing and relying IRBs.

### Federally Funded Research

**Minimal Risk Research:** For federally funded research, UCSF will agree to be the IRB of record *if and only if* the scope of human subject research at the collaborating site is considered minimal risk

[3].

Follow these steps:

Non-affiliated institution

For UCSF to be the IRB of record, the following must occur.

**IRB Application:** Complete the "Outside Site Information Subform," which appears after you indicate that the study involves collaboration with an outside site. Describe the scope of human subjects research at the collaborating site. Also attach a letter from the non-affiliated site deferring IRB approval to the UCSF IRB and the collaborators' training certificates for a Human Subjects Training Course.

**FWA Application:** The engaged institution must designate the UCSF registered Institutional Review Boards [4] on its Federalwide Assurance application [4].

**IRB Authorization Agreement:** Once the FWA has been signed and posted on the OHRP website, the institutions must complete an IRB Authorization Agreement [5]. The IRB Authorization Agreement must designate whether the IRB review is for all research or specific to one study.

The research may begin only after the Institutional Officials at the respective organization have signed the IRB Authorization Agreement [6].

Non-affiliated individual investigator

For UCSF to be the IRB of record, the following must occur:

**IRB Application:** Complete the "Outside Site Information Subform," which appears after you indicate that the study involves collaboration with an outside site. Describe the scope of human subjects research conducted by the non-affiliated investigator. Also attach a letter from the non-affiliated investigator deferring IRB approval to the UCSF IRB and the collaborator's training certificate for a Human Subjects Training Course.

**Individual Investigator Agreement:** The individual investigator signs an Individual Investigator Agreement [7]. This document requires various assurances of the individual investigator, as well as the signature of the FWA Institutional Official.

**Note: Individual Investigator Agreements are rarely approved.**

**Greater Than Minimal Risk Research:** UCSF will not serve as the IRB of record. The site engaged in human subjects research [4] must obtain its own FWA [4] and designate a registered IRB, or register its own IRB.

## **Research That is NOT Federally Funded**

**Minimal Risk Research:** There is no formal mechanism for UCSF to be the IRB of record for non-affiliated institutions when federal funds are not involved. However, UCSF may agree to

be the IRB of record if and only if the scope of human subjects research at the collaborating site is considered minimal risk [3] and discussed in the IRB Application.

Because this type of research is handled on a case-by-case basis, contact the IRB [8] to discuss the details of the proposed study. Also complete the "Outside Site Information Subform," which will appear in the IRB Application if you indicate that the study involves collaboration with outside site.

**Greater Than Minimal Risk Research:** UCSF will not serve as the IRB of record. The site engaged in human subjects research must contract with a private IRB.

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**Links**

[1] <http://irb.ucsf.edu/ucsf-affiliated-institutions>

[2] <http://irb.ucsf.edu/relying-other-irbs>

[3] <http://irb.ucsf.edu/levels-review>

[4] <http://irb.ucsf.edu/working-other-institutions>

[5] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf-irb-authorization.doc>

[6] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf-irb-authorization.doc>

[7] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf-individual-investigator-agreement.doc>

[8] <http://irb.ucsf.edu/contact-us>