



University of California
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Relying on Other IRBs and Current Reliances

What Are IRB Reliances?

Definitions and Responsibilities

University of California IRB Review Reliance/UC MOU

National Cancer Institute Central IRB

Children's Hospital & Research Center Oakland

Community Medical Center IRB in Fresno

Private IRBs: Advarra (former Chesapeake or Schulman), Quorum, and WIRB

What Are IRB Reliances?

Current UCSF policy ^[1] requires that all faculty and staff paid by UCSF for greater than 50% of their effort must have UCSF IRB approval before they begin research using human subjects. This requirement applies regardless of the source of funding and even when no funds are involved, regardless of the site of the study activities.

However, in some cases, UCSF researchers may rely on another IRB to review their human research. UCSF has signed reliance agreements with the following entities on which the UCSF IRB can rely. UCSF will consider additional reliance agreements on a case-by-case basis. Please note that UCSF does not enter into reliances with international sites.

Current IRB Reliances

University of California IRB Review Reliance/UC MOU	Community Medical Center IRB in Fresno
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National Cancer Institute Central IRB (NCI CIRB) Initiative	Private IRBs: Chesapeake, Quorum, Schulman Associates and Western/WIRB (includes Copernicus Group, New England and Midlands IRBs)
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Various Consortia (click for a complete list) ? More info coming soon

Parker Institute ? More info coming soon

- PPHNet
- TrialNet
- NeuroNext (Massachusetts General Hospital)
- StrokeNet (University of Cincinnati)
- TrialNet (Vanderbilt)
- PETAL Prevention and Early Treatment of Acute Lung Injury (Vanderbilt)
- PPHT Pediatric Pulmonary Hypertension Network (Reviewing IRB will vary)
- CARRA Registry, IRBRely (Duke University)
- Cancer Immunotherapy Trials Network CITN (Fred Hutch)
- Rare Lung Disease Consortium RLDC (Cincinnati Children's Hospital)
- Health eHeart ? UCSF is reviewing IRB for NIH and Boston University
- IRBChoice (Vanderbilt)
- RDCRC Rare Disease Clinical Research Consortium (Children's National Medical Center)
- UCDC (Children's National)

Children's Hospital & Research Center Oakland (CHRCO) [2]: CHRCO is a UCSF affiliate, but the relationship between the IRBs has not been formalized. It is our practice is to ask for an IRB Authorization Agreement [3] until there is a written agreement regarding reliances. See below for more info.

Note: In general, UCSF cannot be considered the IRB of record for non-affiliated institutions or investigators. However, there are some limited exceptions when UCSF can serve as IRB of record [4].

Notes for UCSF PIs:

Submit the study in iRIS

When UCSF relies on another IRB, the UCSF PI must submit an abbreviated application in iRIS. See detailed instructions in the individual reliance descriptions below. If another site wishes to rely on the UCSF IRB ^[4], indicate this request in the IRB Application in iRIS.

If using consent forms in non-UCSF format

The UCSF IRB is willing to consider accepting and reviewing consent forms not written in the UCSF format ^[5] in certain circumstances in which the form has been or will be approved by another duly constituted IRB. Use the **Consent Form Checklist for Using a Non-UCSF Consent Form** ^[6] when modifying the consent forms, assent forms, information sheets and recruitment materials. See the Consent Guidelines ^[7] page for more info.

Definitions and Responsibilities

Responsibilities of the Reviewing IRB:

Review submissions

The Reviewing IRB will conduct initial and continuing reviews, and will review amendments/modifications to approved protocol and unanticipated problems or adverse events that may arise.

Can suspend research

The Reviewing IRB will have the authority to suspend the research for failure to comply with conditions of approval or regulatory requirements.

Comply with notification requirements

The Reviewing IRB will notify the Relying IRB of any unanticipated problems, suspensions or terminations of research. The Reviewing IRB will notify the federal or funding agencies of these events consistent with their policies and procedures, copying the Relying IRB on any such correspondence.

Consider COIs and funding

The Reviewing IRB will consider conflicts of interest and confirm, where appropriate, that the application or proposal for human subjects research submitted to the federal Department of Health and Human Services matches the protocol submitted for IRB approval.

Serve as IRB of record

The Reviewing IRB will serve as the IRB of record.

Responsibilities of the Relying IRB: The Relying IRB will rely on the IRB review of the Reviewing IRB. It will not re-review the study.

Another IRB may refuse, on a case-by-case basis, to serve as the IRB of record for another

location or to rely on the review another IRB.

University of California IRB Review Reliance/UC MOU

The Human Research Protection Programs at the University of California Campuses and UC Lawrence Berkeley National Laboratory have instituted a Memorandum of Understanding (MOU) for IRB review of multi-campus human subject research [8].

When applicable, this MOU allows research to be reviewed by the IRB at only one UC location rather than go through the entire IRB process at every UC campus at which the research will take place. In other words, one campus will rely on another campus's IRB review of a study.

Which UC IRB should provide review?

Here are some points to consider when determining which IRB should review the research:

1. Location of the research (beyond recruitment)? Which institution has the most risk? If research is taking place equally at two institutions, then the lead PI should consult with his or her IRB to determine which location should provide IRB review.
2. Where is the primary appointment of the PI?
3. What is the faculty status of the PI?
4. Which institution is the prime grantee?
5. Which IRB has the most expertise to review the study?
6. Do faculty have joint UC appointments?
7. Is the student in a joint UC program?

Registering and creating a new reliance request

All IRB reliance requests must be registered online in the UCOP IRB Reliance Registry [9]. This registry will help streamline the review process across the campuses, create a central repository for all reliances, and allow more transparency for investigators and IRBs at all sites.

Below is a summary on the steps you must take to register and add your study to the registry. Visit the UC IRB Reliance Registry Help page [10] for additional assistance.

Register as a User

All first-time users must register with the UCOP IRB Reliance Registry [9] before creating a new reliance request.

- Go to <http://irbreliance.ucop.edu> [11], click ?Register? and follow the registration steps.

Creating a New Reliance Request

Either the *Reviewing PI* or a *Research Coordinator* at the reviewing campus can create a reliance request.

Create the request

Click the ?Create Request? tab and specify if your study involves Veteran Administration. Complete the info regarding your role in the study and the other required fields marked by an asterisk. Save your entries if you need to log out at any time.

Select the Reviewing PI

If you are the Research Coordinator, you will need to select the Reviewing PI. First, ?Search for a Reviewing PI? by name. If the PI is already registered in the registry, simply select him/her. If the Reviewing PI is not found, you will need to ?Add new Reviewing PI.?

Student Investigators identify as a Research Coordinator

If you are a Student Investigator for the Reviewing or Relying Campus, you must identify yourself as a Research Coordinator and your faculty sponsor as the PI. You will have access to the online reliance request, but only PIs may sign off on the reliance via the Registry.

Invite the Relying PI(s)

Invite the Relying PI(s) from other campuses. First, ?Search for a Relying PI? by name and campus. If the PI is already registered in the registry, simply select him/her. If the Relying PI is not found, you will need to ?Add a new Relying PI.? The Registry will notify the Relying PI(s) via email to register and confirm their involvement in the study. Email addresses must be entered accurately ? there is no bounce-back function.

Sign off and submit Reliance Request in iRIS

Once all Reviewing and Relying PIs have registered and have been added to the study, the *Reviewing PI* will be able to sign off on the Reliance Request form.

The *Reviewing PI* will need to convert the Reliance Request form to a PDF and submit it with the submission in iRIS.

IRB Functions

Reviewing IRB's role

Upon approval of the study, the *Reviewing IRB* will add the approval/expiration date, approved protocol, approval letter and any applicable consent forms to the study?s Registry record. An automated email notice will be sent to all PIs and the Relying IRB.

Relying IRB's role The *Relying IRB* will review the documents and accept or deny the reliance via the Registry. If accepted, the Relying IRB will upload an Accept to Rely letter, creating an Active Reliance. All PIs and the Reviewing IRB will be notified of this decision via automated email.

Submitting continuing reviews and modifications

If the study does not already have an active reliance in the registry, follow the steps above for creating a new reliance request.

Continuing reviews

If the study already has an active reliance in the registry, the *Reviewing PI* should submit a continuing review submission ^[12] via iRIS as usual. Upon approval, the Reviewing IRB will update the study's expiration date in the Registry.

Please submit your continuing review in a timely fashion. **If the study expires, no relying UC site will be able to continue work on the study until approval is obtained.**

Modifications/amendments

Submit any modifications ^[13] to the *Reviewing IRB*, which will update any changes to the study in the Registry. The Relying PI is responsible for informing the Reviewing PI of any necessary modifications.

Post-approval event reporting (adverse events, protocol violations, etc.)

Submit all post approval event reports ? including adverse or unanticipated events, protocol violations, or other reportable incidents ? to the *Reviewing IRB*. The Relying PI is responsible for informing the Reviewing PI of any reportable events, protocol violations or other reportable incidents.

Submitting at UCSF

UCSF as Reviewing IRB and UCSF PI as Reviewing PI

When UCSF is the reviewing IRB for a study being conducted at both UCSF and an other UC site(s), the UCSF PI should complete a full IRB application in iRIS. Follow these instructions for submitting a new study ^[14]. Also provide the following information in iRIS:

1. In section 6 of the IRB Application, please indicate that you are working with another UC campus.
2. You will also need to clarify which UC campuses are involved and indicate that the other UC campus(es) are requesting to rely on UCSF's IRB.
3. In the remainder of the IRB Application, clarify what work is being done at the other UC campus(es). To keep this organized use headers to indicate what applies to specific sites or provide a general statement in the section that says something like, "UCLA with use the same

recruitment techniques as UCSF.?

4. Upload a PDF of the UCOP IRB Reliance Registry ^[9] page with the corresponding information in "Other Study Document" in iRIS; then attach this document to your submission.
5. The Reviewing IRB will review the study as described above, and accept or deny the reliance. The Relying IRB will then need to accept or deny the reliance. Once the Relying IRB accepts, the relying campus can begin the study procedures.

UCSF as Relying IRB and UCSF PI as Relying PI ^[15]

When UCSF investigators wish to rely on the another UC IRB, the UCSF PI should complete an abbreviated IRB application in iRIS:

1. In the IRB Application section 6, answer "Yes" to this question: "Relying on an external IRB: Does this application include a request to rely on a central IRB (other than the NCI) or an external IRB (UC, commercial, or institutional)."
2. In the next section mark which UC you wish to rely on.
3. Complete all remaining sections in the IRB application with information specific to the UCSF site.
4. Attach a PDF of the Registry information to the other study documents section of iRIS.
5. The Reviewing and Relying IRBs will review the study as described above and accept or deny the reliance.

National Cancer Institute Central IRB (NCI CIRB) Initiative

The CIRB Initiative is sponsored by the NCI in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The CIRB provides an innovative approach to the IRB review of adult and pediatric national multi-center cancer treatment trials that significantly speeds up IRB approval and yet maintains a high level of protection for the human research participants. For full details about this initiative, please see the NCI CIRB Initiative ^[16] website.

The CIRB provides expert IRB review at the national level before the Cooperative Group distributes the protocol to local investigators. UCSF has a formal agreement with the NCI CIRB, so investigators who wish to participate in the Cooperative Group Trials reviewed by the NCI CIRB ^[17] may take advantage of these reviews.

These reviews include: Adult CIRB, Late Phase Emphasis Adult CIRB and Early Phase Emphasis Pediatric CIRB.

How the CIRB works

For complete information, visit the How it Works ^[18] page on the CIRB website.

1. The Adult or Pediatric CIRB receives a completed application, protocol, informed consent form and related materials from the Cooperative Group via the NCI.
2. The full CIRB Board conducts initial review and approves the protocol.
3. After the protocol is activated by the Cooperative Group, all review documents are posted on the CTSU website ^[19] for access by participating institutions.
4. A local investigator at a participating institution decides to join the clinical trial for a CIRB-approved protocol. The UCSF Cancer Center investigator downloads the application packet and submits to the Cancer Center PRC.

Once the Cancer Center PRC approves the protocol, the investigator submits an abbreviated application to the UCSF IRB via iRIS. The UCSF IRB office reviews the submission and confirms CITI human subjects protection training ^[20] and other applicable ancillary approvals (i.e. Radiation Safety Committee or Biosafety Committee).

5. The UCSF IRB acknowledges the submission and provides notification that UCSF accepts to rely on the CIRB.
6. The CIRB becomes the IRB of Record for this protocol and is responsible for continuing review as well as review of subsequent amendments, potential unanticipated problems, or serious or continuing protocol noncompliance as defined by the CIRB. *The UCSF HRPP will receive reports of unanticipated problems and serious and/or continuing noncompliance from the CIRB.*

Procedures for UCSF Cancer Center PI use of NCI CIRB

- 1. Each UCSF participating cooperative group PI must register with the NCI CIRB through the UCSF IRB.** Registration is needed in order to be able to access the full NCI CIRB website and to receive correspondence from the NCI CIRB. UCSF has already forwarded to the NCI CIRB many of the names of the Cooperative Group PIs, as well as several of the names of the study coordinators and any other individuals who work the PI and need to receive correspondence from the CIRB. If any additional PIs or contacts need to be registered, please complete the linked NCI Contact form ^[21].
- 2. PI reviews listing of CIRB approved protocols.** These lists are available at the CTSU website ^[19]. Investigators may choose a new study, or they may transfer a study to CIRB if they have a study active on the list. ???
- 3. PI downloads protocol from CTSU Website.** If the PI is interested in participating in one or more of these protocols or transferring an IRB-approved protocol to CIRB, he or she should download the protocol and consent documents.

Important Note: Notify the Cancer Center Protocol Review Committee [22] and obtain its approval for the study to occur at UCSF before submitting the abbreviated application to the UCSF IRB.

4. PI makes the NCI consent form UCSF-specific. Please see the local boilerplate informed consent template. The UCSF-specific consent and assents forms should be submitted to the UCSF IRB. Note that UCSF policy for obtaining assent should be followed.

<https://irb.ucsf.edu/children-and-minors-research> [23]

Important Note: The NCI allows only local boilerplate additions to the informed consent that have been previously approved by the NCI.

5. PI completes an abbreviated application in iRIS. In section 5, please be sure to indicate "Yes" when asked "This is a CIRB study."?? Please attach UCSF specific consent forms to the submission.

Important Note: The abbreviated application form requests information about other related committee approvals that are needed. If Radiation Safety and/or Biosafety Approvals are needed, these must be in place before the UCSF IRB can agree to rely on the CIRB for the approval of the study. Also, Key Personnel must complete the online CITI human subjects protection training [20].

IRB review and acknowledgement procedures

1. The UCSF IRB Notifies PI of Acceptance or Rejection of CIRB Approval. After reviewing the abbreviated application, and confirming Human Subjects Protection Training and other applicable approvals are in place, the UCSF IRB acknowledges the submission and issues an acknowledgement letter confirming that UCSF agrees to rely on the CIRB for this study.

Important Note: The PI may begin enrolling patients as soon as the CIRB registration email notification is received.??

2. All continuing review and modification applications are submitted directly to the NCI CIRB. Please only submit a modification to the UCSF IRB for a change of PI [13]. The UCSF IRB will acknowledge the submission in iRIS but will not issue an approval or acknowledgement letter. The UCSF PI will also be able to view the acknowledgement in iRIS. Also submit a Study Closeout Report [24] to the UCSF IRB.

CIRB responsibilities

- **Perform initial reviews** of new research studies, discuss issues with the lead organization and Study Chair, and make final decision of approval or disapproval of the study.
- **Maintain and make accessible to designated IRBs the CIRB review materials.**

- **Carry out continuing reviews, and reviews of submitted serious adverse events, protocol amendments, DSMB reports** and any other documents submitted by the lead organization or Study Chair.
- **Notify each local institution** PI of any new materials and any changes in the study approval status.
- **Additional responsibilities** are available on the NCI CIRB website [18].

PI responsibilities

- **Assume ultimate responsibility for all aspects of the study.** Please refer to the Responsibilities of PIs and CRCs [25] page for full details of these responsibilities.
- **Maintain a copy of the UCSF IRB acknowledgement letter** in the study file in case the UCSF HRPP, the UCSF Audit Services, the federal government or the funding agency audits the study.
- **Review CIRB website regularly** to keep current with all information including amendments to CIRB-approved studies.
- **Submit internal (on-site) adverse event, protocol violations and incident reports** to the CIRB.
- **Submit continuing review and modification materials** to the CIRB in a timely manner.

Notify CIRB and/or UCSF IRB if any parts of this process are unclear. In this way, improvements and revisions can be made to ensure that process will be both efficient and effective. For NCI CIRB questions, email CoopGroupRequests@cc.ucsf.edu [26]. For UCSF IRB questions, email irb@ucsf.edu [27].

IRB Affiliation with Children's Hospital & Research Center Oakland (CHRCO)

UCSF and CHRCO [28] are able to rely on each other for IRB review. Either the UCSF or CHRCO IRB can be the reviewing IRB, depending on numerous factors. Typically, we recommend the IRB of record to be the main site for the research.

While CHRCO is a UCSF affiliate, the relationship between the IRBs has not been formalized. It is our practice is to ask for an IRB Authorization Agreement [3] until there is a written agreement regarding reliances. See the [When UCSF Can Serve as IRB of Record](#) [4] page and contact our office for more information.

Please expect changes to these processes as the merger between UCSF and CHRCO evolves. Currently the IRB offices continue to oversee and manage the research being conducted at each site.

UCSF as IRB of Record

Submission and review process at UCSF

When UCSF is the reviewing IRB for a study being conducted at both UCSF and CHRCO, the UCSF PI should complete a full IRB application in iRIS. Follow these instructions for submitting a new study ^[14].

1. In the "Sites" section of the IRB application, please indicate that you are working with an outside institution, and list Children's Hospital & Research Center Oakland as an Outside Site. You will need to select that CHRCO is requesting to rely on UCSF as the IRB of record in this section.
2. The application will branch to provide an additional section to provide information on the scope of work for the CHRCO Investigators.
3. Attach the CITI training ^[20] completion certificates for the CHRCO investigators as Other Study Documents with your IRB submission.

Submission and review process at CHRCO

Guidelines under development. Please contact CHRCO ^[29].

CHRCO as IRB of Record

Submission and review process at UCSF

When UCSF investigators wish to rely on the CHRCO IRB for a study being conducted at both UCSF and CHRCO, the UCSF PI should complete an abbreviated IRB application in iRIS. Follow these Instructions for submitting a new study:

1. In the "Key Study Personnel" section of the IRB application, describe the study activities for the UCSF PI under Description of Study Responsibilities.
2. In the "Sites, Programs, Resources, and External IRB Review" section, check "Yes" to the question that asks "This application includes a request to rely on another IRB (other than NCI CIRB)."
3. Complete all remaining sections in the IRB application.
4. Attach the CHRCO IRB approval letter as an Other Study Document with the IRB submission.

Submission and review process at CHRCO

Guidelines under development. Please contact CHRCO ^[29].

Community Medical Center IRB in Fresno

There is a Memorandum of Understanding (MOU) between the Community Medical Center IRB in Fresno and the University of California that applies to all categories of human research (that is, full committee, expedited and exempt [30] research). When applicable, the MOU allows research to be reviewed only by the Community Medical Centers IRB rather than having to also be reviewed by the UCSF IRB.

What research is eligible for this MOU?

To be eligible for this MOU, the following conditions must be met:

- The research will be conducted at any of the Community Medical Centers (CMC) facilities, or involves identifiable data or specimens from any CMC facilities.
- No research will be conducted at UCSF or any of its Bay Area Affiliates.
- The research must be funded through UCSF, or conducted by UCSF faculty.

Submission and review process

UCSF PI

- Submits an application to the Community Medical Centers? IRB according to that IRB's guidelines. The PI should indicate to the Community Medical Centers? IRB that the study is funded through UCSF.
 - Follow the standards and guidelines of the Community Medical Centers? IRB for the reporting of any post approval events. These include adverse events, other safety information, and/or protocol violations or incidents.
 - Follow the standards and guidelines of the Community Medical Centers? IRB for submitting amendments and renewal applications.
-

Community Medical Centers? IRB

- Notifies the UCSF HRPP of approvals that fall under this MOU, and forwards a copy of their approval letter and the approved application packet to the UCSF HRPP.
 - Is the IRB of Record for studies reviewed under this MOU and is responsible for continuing review as well as review of subsequent amendments and serious adverse events.
-

UCSF Fresno Grants and Research Office

- Is responsible for comparing grant applications with corresponding CMC IRB applications.
 - Is responsible for collecting and forwarding financial disclosure documents to the UCSF COIAC.
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-
- Will record approvals taking place under this MOU and maintain copies of approval documentation.

UCSF HRPP

IMPORTANT NOTE: *The UCSF HRPP will not issue approval letters for studies reviewed under this MOU.* Investigators should use the approval letter from the Community Medical Centers? IRB to document IRB approval.

UCSF Fresno faculty eligible to submit IRB applications [15]

UCSF Fresno Faculty eligibility is based on the UCSF requirements found **here** [31].

Note that UCSF Fresno is a department of the UCSF School of Medicine. If you have any questions please contact Sharon Hutchinson [32].

Private IRBs

UCSF has reliance agreements with several private IRBs. If a study is eligible for private IRB review and the PI chooses this option, the PI will be responsible for submitting the study to the UCSF IRB and the private IRB. These submissions can occur in parallel, but the private IRB will not review the study until UCSF has confirmed that the study is eligible.

What studies are eligible for private IRB review?

Studies that meet the following criteria are eligible for private IRB review:

- Clinical trial phases II*, III, or IV
- Industry-funded, Not-for-profit-funded, Federally-funded**
- Have approval from a UCSF scientific review committee, where required:
 - Cancer Center Protocol Review Committee (PRC) [22]
 - Clinical Research Services (CRS) Advisory Committees [33]

* temporarily added 12/1/17 to 6/30/18, extending through 12/31/2019

** temporarily added from 7/1/2018 to 12/31/18

Exceptions: Research involving the following must be reviewed by the UCSF IRB

- Neonates***
- Transplant research***
- Surgical techniques or procedures
- Stem cell therapies
- Gene transfer, gene therapy
- Investigational radiologic procedures

- Research involving SFVAMC ^[34]

***If you are doing transplant or neonate research and are interested in relying on a private IRB, contact Laurie Herraiz at 415-476-1814 or IRB@ucsf.edu ^[35] to see if an exception can be made for your study.

The HRPP reserves the right to make additional exceptions and has final say on whether research must be reviewed by IRB.

UCSF submission and review process

The following steps should be followed for all studies that intend to rely on a private IRB for review.

1. The PI submits an abbreviated IRB application through iRIS.

IRB Application Form:

- In the "Sites, Programs, Resources, and External IRB Review" section, answer Yes to this question: "This application includes a request to rely on another IRB (other than NCI CIRB)."
- In the "Relying on Another IRB" section, select the applicable private IRB or select "Other" and specify the IRB in the text box.

Attachments: Attach the sponsor's protocol as an Other Study Document. Submit all other attachments ? including the consent form(s) ? directly to the private IRB. Note: Use the UCSF consent form templates ^[5] (see Important Notes below).

2. The HRPP staff reviews the study to confirm eligibility and generates an acknowledgement letter allowing the UCSF PI to rely. **The PI should provide this letter to the private IRB.**

3. Submit a Study Closeout Report ^[24] to the UCSF IRB when the study is closed with the private IRB.

Important Notes:

- Only one submission to the UCSF IRB is necessary. Once eligibility has been confirmed, all future submissions and reporting are between the PI and the private IRB.?
- The private IRB will not review until HRPP confirms eligibility.?
- The consent forms submitted to the private IRB must follow the UCSF consent templates ^[5]. You can also use the following checklist as a guide: Consent Form Checklist for Using a Non-UCSF Consent Form ^[6]. The private IRB is responsible for ensuring consistency with that template.
- The study team will not receive continuing review reminders from the HRPP; however, the private IRB will email reminders.

Other reviews

Conflicts of Interest [36]: HRPP will forward COIAC findings and management plans, if any, to the private IRB. The private IRB has final say on management plan for research they oversee. The management plan may require a modification to the study.

Radiation Safety Committee [37]: Radiation Safety may require specific consent form wording. This may require a modification to the study.

Other committees, departments and personnel: They will continue to have their own review requirements.

Submission and Review Process by Each Private IRB

Western IRB (WIRB) ? includes Copernicus Group IRB, New England IRB and Midlands IRB

1. The PI submits an application to WIRB through WIRB's online electronic system. Register for an account [38] on the WIRB site. WIRB will train PIs and their staff on how to use this system.
2. WIRB reviews the study.
3. WIRB notifies PI and HRPP of approval.

Advarra

1. The PI submits an application to Advarra IRB through Advarra IRB's online electronic system, CIRBI [39]. The steps for login and starting a new submission are summarized below. Advarra IRB can train PIs and their staff on how to use this system.

- Go to the CIRBI web site [40], click "sign up" and create a user profile. Then you will be issued credentials to access the system.
- After you register, you will be directed to your home page whenever you log into CIRBI [40], and will be able to create and access your studies. NOTE: Any colleagues who want access to the study submission in CIRBI will need to register before you begin to create it, so that they are in your company directory and you can select them as contacts while creating your submission. The PI also needs register in advance.
- Click ?Create new submission? to start a new protocol submission.
 - Select the entry ?Investigator/Site Application? to provide information about your PI, as well as your site.
 - The applications are based on smart forms, so you will not be able to advance to the next page of questions unless you answer all required questions (with a red asterisk) on each page. However, there is a solution as you create your submission: above the white box of questions on each page, you will see a gray bar that says ?Save, Exit, etc.? The last choice is ?Jump To.? If you click on that, a drop down list of all pages of the application will appear, and you can move from page to page without having to complete each one until you are ready to submit the application.

2. Advarra IRB reviews the study.
3. Advarra IRB notifies PI and HRPP of approval.

Quorum IRB

Guidelines are under development. Please contact us^[41] with questions.

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Source URL: <https://irb.ucsf.edu/relying-other-irbs>

Links

- [1] <https://irb.ucsf.edu/research-needing-irb-review>
- [2] <https://irb.ucsf.edu/#oakland>
- [3] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf-irb-authorization.doc>
- [4] <https://irb.ucsf.edu/when-ucsf-can-serve-irb-record>
- [5] <https://irb.ucsf.edu/consent-and-assent-form-templates>
- [6] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/checklist-non-ucsf-consent.pdf>
- [7] <https://irb.ucsf.edu/consent-guidelines>
- [8] http://www.ucop.edu/research-policy-analysis-coordination/_files/mou-human-subjects-protection-programs.pdf
- [9] <http://irbreliance.ucop.edu/>
- [10] <https://irbreliance.ucop.edu/site/help>
- [11] <https://irbreliance.ucop.edu/>
- [12] <https://irb.ucsf.edu/continuing-review>
- [13] <https://irb.ucsf.edu/modification>
- [14] <https://irb.ucsf.edu/new-study>
- [15] <https://irb.ucsf.edu/#>
- [16] <http://www.ncicirb.org/>
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- [18] <https://ncicirb.org/cirb/howItWorks.action>
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- [22] <http://cancer.ucsf.edu/itr/itr-prc>
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