

COMIRB as sIRB

This document provides background and instructions for researchers who would like COMIRB to serve as a single IRB (sIRB) for research performed at external sites.

[NIH policy](#) establishes the expectation that NIH-funded multi-site research be overseen by a sIRB. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. It does not apply to career development, research training or fellowship awards. Applicants are expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH.

See [Template sIRB Plan when Proposing COMIRB serve as sIRB](#).

COMIRB recognizes the need for efficient implementation for multi-site studies while ensuring the protection of human subjects. The University of Colorado Denver | Anschutz is a participating institution in SMART IRB, an IRB reliance network developed to harmonize and streamline the IRB review process for multi-site studies, while ensuring a high level of protection for research participants.

To use an IRB other than COMIRB, email: ExternalIRB@ucdenver.edu.

Basic requirements for COMIRB to serve as sIRB:

- The research must require full board or expedited IRB review.
- The research must involve the University of Colorado Denver or one of our affiliates.
- The relying site must have an active [Federalwide Assurance \(FWA\)](#) with the Office for Human Research Protections.
- The PI on the COMIRB application must assume additional responsibilities for IRB-related oversight of relying sites. These additional responsibilities are listed on the COMIRB Lead IRB PI Responsibilities form.
- The external institution(s) must be willing to rely on COMIRB as sIRB.

COMIRB will not serve as sIRB:

- For exempt research,
- For non-human subjects research determinations, including quality improvement, quality assurance, or program evaluations,
- For participating sites which are not engaged in human subjects research,
- For institutions that do not have an FWA,
- For international sites,
- For unfunded clinical investigations

- For any study in which COMIRB cannot assure subject safety and full regulatory compliance.

If COMIRB serves as sIRB, research may not begin at a relying site until both:

1. COMIRB has approved the additional site, along with any site-specific documents, and
2. The relying institution and the University of Colorado Denver | Anschutz have both signed an IRB Authorization or similar agreement (e.g., Smart IRB letter) for the specific study.

Instructions for requesting that COMIRB serve as sIRB:

1. Discuss your study with COMIRB leadership. Contact COMIRB@ucdenver.edu or 303-724-1055. Please forward a copy of the protocol or grant proposal, and a list of the potential sites. For complicated submissions (e.g., clinical trials, multiple sites in different states), we are always happy to schedule a meeting to work through any details.

If COMIRB agrees it can serve as sIRB:

2. Ask your relying co-investigators to contact their local IRB offices to see if their IRBs are willing to rely on COMIRB. Provide your co-investigators with a copy of your protocol, and any other information your co-investigators will need to provide to their local IRB offices.

Note: If COMIRB serves as sIRB, this does not mean your co-investigators do not have to submit information about the study to their local IRBs.

3. COMIRB staff will assist in obtaining the appropriate reliance agreements from the IRB office at the non-affiliated site. The relying site will usually have specific processes their investigators must follow before a reliance agreement will be signed.

Requirements for the COMIRB Submissions:

1. Initial Review: Get your study approved with COMIRB for our site(s) first.
 - a. In the Application Form, under Section F(b), Non-Affiliate Performance Sites: Answer “Yes.”
 - b. Attach Lead IRB PI Responsibilities checklist, signed by the PI (if not previously submitted – only needs to be submitted once.)
 - c. In the Application Form, under Attachment A, IRB Oversight: Answer “No” if any non-affiliated site will rely on COMIRB instead of seeking their own IRB approval. Answer the resulting questions in the smart form as appropriate. In the table labeled, “Attachment A1,” list all of the sites for which COMIRB will serve as Single IRB, and select “Pending” from the dropdown menu in the “Completed IRB

Authorization” column for each site. This response should only be changed to “Yes” after both institutions have signed a reliance agreement.

2. Before submitting amendments to add sites:
 - a. Distribute the IRB-approved protocol, application and any other appropriate IRB-approved documents to the relying site(s).
 - b. Finalize any site-level differences (e.g., with the recruitment and consent process)
3. Submit an amendment to add relying sites.
 - a. Adding one site at a time is preferred but not required.
 - b. Attach a cover letter confirming that the relying site PI has contacted the relying site IRB office about relying on COMIRB for IRB approval, and the site PI has provided all documents the relying IRB requires.
 - c. Update Attachment A as appropriate, changing “Pending” to “Yes.”
 - d. Complete and attach a “Relying Site Details” form available [here](#), make sure study activities taking place at non-affiliated sites which are relying on COMIRB are adequately described, and that a PI for the non-affiliated site is identified. This is particularly important if different sites have different roles on the overall study. If necessary, you may need to provide site details in a separate form.
4. Depending on the non-affiliated site, and the study activities taking place at the site, supplemental (“local context”) information may be required from the non-affiliated site. COMIRB will initiate this directly with the relying IRB.
5. Non-affiliated investigators: List non-affiliated investigators on the “Relying Site Details” form. Do not list non-affiliated investigators on the Personnel Form in InfoEd.

[IRB Reliance Agreements:](#)

Once your submission is received, COMIRB will contact the relying site’s IRB office(s) to obtain Local Context information and obtain an IRB reliance agreement. There are several types of IRB Reliance Agreements. During COMIRB’s review of the request to serve as IRB of record, the appropriate IRB Reliance Agreement will be selected.

1. [SmartIRB Acknowledgement](#): If the non-affiliated site is a [participating institution](#) in the SmartIRB network, COMIRB will serve as lead IRB under the terms of the SmartIRB Agreement. The acknowledgement letter is signed by the SmartIRB Point of Contact at each institution. Depending on the risk and complexity of the research, COMIRB may require the use of [IREx](#) to ensure clear communications between relying sites.
2. [IRB Authorization Agreement](#): This agreement will be used for institutions that are not part of the Smart IRB network. It lists responsibilities for both the reviewing institution and the relying institution, and requires the non-affiliated site to take responsibility for ensuring their personnel have completed required human subjects training and conflict of interest disclosures, and to report any conflicts of interest to COMIRB.

3. Memorandum of Understanding (MOU) or other Agreements: The University has MOUs or similar agreements for IRB review with some of the institutions and networks with which our researchers regularly collaborate. IRB Reliance Agreements may not be necessary in these cases.

Frequently Asked Questions:

Q: I am submitting a proposal to NIH and I need a letter of support regarding the use of a single IRB. Where do I get this?

A: If COMIRB is being considered as the single IRB for your proposal, email a copy of your proposal to COMIRB@ucdenver.edu. If the Director agrees COMIRB can serve as the single IRB, the Director will send you a letter of support. If the university is being asked to cede to another IRB, email a copy of your proposal to ExternalIRB@ucdenver.edu for a letter of support.

Q: Will COMIRB serve as sIRB for multi-site research that is not NIH funded?

A: COMIRB will consider serving as sIRB for research for multi-site research that is not NIH funded. However, COMIRB may be more restrictive in these cases. COMIRB will not serve as sIRB for unfunded clinical investigations. If the research is insufficiently funded in relationship to the additional obligations required by sIRB, COMIRB may not be able to commit to serving as sIRB.

Q: The University of Colorado Denver | Anschutz is the primary recipient of the award. Does that mean COMIRB must serve as sIRB?

A: No, COMIRB is not required to serve as sIRB. There are three basic options for selecting the sIRB for NIH-funded research: Using the IRB from the institution that is the primary recipient of the award, using a commercial IRB, or using an IRB from one of the sub-recipients of the award. If COMIRB cannot serve as sIRB, researchers should pursue these other options.

Q: If COMIRB is serving as sIRB, are participating sites required to rely on COMIRB?

A: No, there are many reasons a participating site may not be able to rely on COMIRB. Also, COMIRB may not be willing to serve as sIRB for some sites. For example, COMIRB will not serve as sIRB for a site that does not have an FWA.

Q: If COMIRB serves as sIRB, does that mean the external PIs do not need approval from their local IRB offices?

A: No. All site PIs are always required to contact their local IRB offices about relying on COMIRB. Each local IRB office will have a process in place to review the research before deciding to rely on COMIRB. The specifics of that process will vary from IRB to IRB.

Q: What is SmartIRB?

A: SmartIRB is a platform to help IRBs rely on one another. Over 500 institutions have joined. The University of Colorado, Denver | Anschutz Medical Campus, Children's Hospital Colorado, Denver Health and Hospital Authority, and National Jewish Health have all joined SmartIRB. More information is available at smartirb.org.

Q: I am from an external site that does not have an IRB. Can COMIRB serve as our IRB?

A: COMIRB can only serve as the IRB of record for a non-affiliated site when one of our affiliates is engaged in the research.