

## Lead PI Responsibilities when COMIRB Serves as Single IRB

As the Lead Principle Investigator for a study for which COMIRB is serving as Single IRB (sIRB) for some or all sites, you assume additional responsibilities. To acknowledge these additional responsibilities, please sign and upload this form with your COMIRB application. This form need only be uploaded once.

Your initial responsibilities include:

1. Contact COMIRB and discuss whether COMIRB can act as sIRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
  - Provide COMIRB a copy of the protocol or funding proposal.
  - Identify all sites and site PIs that will be involved and describe their roles in the study.

If COMIRB agrees it can serve as sIRB for all or some sites:

2. Get your study approved by COMIRB for our affiliated site(s) first. Add relying sites via amendments after initial approval.
3. Provide the IRB-approved protocol, template consent document(s) (if any), and any other necessary study documentation to your collaborating PIs.
4. Instruct collaborating PIs to contact their local IRB offices to inquire about relying on COMIRB. Provides the Site Investigators with [COMIRB policies and Procedures](#).
5. Confirm with collaborating PIs whether site-specific consent document(s) or any other site-specific documents will be necessary. If so, work with collaborating study teams to draft these additional documents.
6. Submit an amendment to COMIRB to add each relying site. Contact COMIRB for advice on whether to submit each site as a separate amendment. Include all information necessary for COMIRB to approve the relying site. This may include site-specific study materials, including site-specific consent documents. Identify the site PI and describe the scope of work for each site.

Your additional responsibilities throughout the study:

- Promptly respond to questions or requests for information from relying study teams or relying IRB offices.
- Provide Relying Site Study Teams with the COMIRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- Prepare and submit COMIRB applications on behalf of all relying sites, including initial reviews, local amendments, investigator updates, local reportable events, and study-wide information for continuing review.

- Obtain and collate information from Relying Site Study Teams, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
- Assist Relying Site Study Teams in ensuring consent documents include applicable site-specific required language, and are approved by COMIRB prior to use.
- Notify Site Investigators of all COMIRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
- When agreed upon in coordination with the COMIRB, promptly report to the Relying Site PI any unanticipated problems involving risks to subjects or others, research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research.
- Obtain and collect information from Relying Site Study Teams needed for continuing review. If the Relying Site Study Team does not provide you with the required information before the continuing review application is reviewed by COMIRB, report the absence of this information as part of the continuing review. If IRB approval expires for any Relying Site, notify the affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
- Provide access, upon request, to study records for audit by the Relying Institution. Notify COMIRB of any such monitoring or audit requests.
- Follow all requirements of the Relying Institution with regard to sIRB review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

Failure to adhere to these responsibilities may result in termination of COMIRB’s oversight as sIRB at some or all relying sites.

I understand and accept the above responsibilities,

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Signature, Principal Investigator

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Date