

Relying Site Study Teams

The Relying Site Study Teams, which include Site Investigators, are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded:

- Following all requirements of their home institution with regard to ceded review, such as ensuring other reviews or sign-offs required by the institution have been completed before a study is activated.
- Promptly responding to questions or requests for information from the Lead Study Team (or designee) as well as from the Reviewing IRB through the communication mechanism(s) established by these entities.
- Participating in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or home institution.
- Working with the Lead Study Team and the POC from their home institution, as applicable, to incorporate site-specific required language into the consent template to be used at their institution.
- Providing the sponsored programs office at their institution with documentation that IRB oversight for a study has been ceded to and approved by an IRB external to their home institution.
- Providing the POC from their home institution with information regarding local Site Investigator or other Relying Site Study Team personnel changes.
- Reporting to their home institution POC any changes in conflict of interest (COI) disclosures and resulting changes in COI management plans related to the Research (i.e., the specific study or studies ceded to the Reviewing IRB).
- Promptly reporting to the Lead Study Team (or designee) any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
- Reporting to the Lead Study Team (or designee) any changes (including funding changes and personnel changes), reportable events, and continuing review progress reports, for submission to the Reviewing IRB in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
- Promptly reporting to the Overall PI via the Lead Study Team (or designee) any unanticipated problems involving risks to subjects or others, subject injuries related to the research, or significant complaints that could impact the conduct of the Research (i.e., the specific study or studies ceded to the Reviewing IRB) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions. Significant complaints are defined as those that cannot be resolved by the study team and a) suggest an increased or unexpected new risk or harm or b) change the risk/benefit ratio of the Research. Other complaints should be reported in accordance with the Reviewing IRB's policies and procedures.
- Promptly reporting to the Overall PI via the Lead Study Team (or designee) any potential noncompliance that occurs in relation to the Research (i.e., the specific study or studies ceded to the Reviewing IRB) in accordance with the Reviewing IRB's policies and procedures for timing of submission and content of such submissions.
- Providing, upon request, access to study records for audit by the local institution, the Reviewing IRB's institution, and other regulatory or monitoring entities.