

DEFINITIONS / ROLES AND RESPONSIBILITIES

- **Single IRB (sIRB):** One IRB of record (or *Reviewing IRB*), selected on a study-by-study basis, provides the ethical review for all sites participating in a specific multisite study.
- **Relying IRB:** IRB that relies on the reviewing IRB for the regulatory reviews. The relying IRB is still responsible for institutional reviews (COI, Radiation, Biosafety, Privacy, and others).
- **Reviewing IRB:** The selected IRB of record that conducts the ethical review for participating sites of the multi-site study, including initial reviews, modifications, continuing reviews, and reportable events.
- **Lead PI:** Responsible for the communication and overall conduct of the study and regulatory compliance. The Lead PI will be submitting the regulatory IRB submissions on behalf of all the sites relying on the reviewing IRB. (Note: The Lead PI may not always be associated with the reviewing IRB, but the Lead PI's responsibilities nevertheless remain the same.) [Lead PI responsibilities](#)
- **Relying PI:** Responsible for providing the Lead PI with necessary information according to the reviewing IRB's policies and procedures so the reviewing IRB can conduct an IRB review. The relying PI must know what is also required from their local relying IRB. [Relying PI responsibilities](#)
- **Central IRB:** IRB of record (also known as the *Reviewing IRB*) provides the ethical review for all sites participating in more than one multisite study. The sites are usually in a network, consortium or particular program, e.g. NCI's CIRB.
- **Commercial IRB:** Commercial or independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects, e.g., Quorum IRB, Ethical and Independent Review (E&I Review), Western IRB (WIRB).

HOW TO GET STARTED TO RELY ON A sIRB

The Protocol Director (PD) is required to submit a sIRB [eProtocol](#) (eP) application to request reliance on a sIRB.

The following is required in the sIRB eP application:

- a. IRB Authorization Agreement (IAA) signed by the reviewing sIRB Institution
- b. Federal grant (when Stanford is the prime awardee)
- c. Current sIRB approved study protocol
- d. Current sIRB approval letter
- e. Informed consent document(s) with Stanford required [consent language](#)
- f. Local context document (when requested by sIRB)

Stanford University HRPP Guidance	STANFORD SOPs FOR RELYING ON A SINGLE IRB (sIRB)	GUI-03H24 2/2
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Note: When possible, documents need to be complete or fully executed at the time of your initial eP submission.

WHEN IS THE RELIANCE COMPLETE

A Reliance Letter will be issued when the sIRB application is complete and the IAA has been fully executed.

The Reliance Letter will also be available in eP in the Event History section. This letter, along with the sIRB approval letter, must be provided to RMG/OSR and others as needed.

STANFORD IRB

When Stanford IRB is **not** the IRB of record, the PD must follow the Stanford eProtocol Obligations listed in the sIRB eP application, **as well as the reviewing sIRB's Policies and Procedures.**

Stanford IRB requires the following submissions:

- Determinations made by the sIRB of serious or continuing noncompliance that take place at Stanford
- Determinations made by the sIRB of unanticipated problems that take place at Stanford
- Unresolved participant complaints at Stanford
- Change of Stanford Protocol Director
- Changes in Conflict of Interest
- Notification to the Stanford IRB when study is closed, terminated or suspended
- Notification of external audits (e.g., FDA)

LINKS

- [eProtocol](#)
- [Stanford required consent form language](#)
- [Final NIH Policy on Single IRB](#)