DEFINITIONS / ROLES AND RESPONSIBILITIES

- **Single IRB (sIRB) Review Process** One IRB of record, selected on a study-by-study basis, provides the ethical review for all sites participating in a specific multisite or cooperative 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., Advarra IRB, Ethical and Independent Review (E&I Review), Western IRB (WIRB).

HOW TO GET STARTED TO RELY ON AN EXTERNAL IRB

The Protocol Director (PD) is required to submit an sIRB eProtocol (eP) application to request reliance on an external IRB.

The following is required in the sIRB eProtocol application:

a. IRB Authorization Agreement (IAA)
b. Current Reviewing IRB approved study protocol
c. Initial Reviewing IRB approval letter
d. Informed consent document(s) with Stanford required consent language
e. Local context document (when requested by Reviewing IRB)

WHEN IS THE RELIANCE COMPLETE

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

The Reliance Letter will also be available in eProtocol in the Event History section. This letter, along with the Reviewing IRB 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 eProtocol application, ***as well as the Reviewing IRB's Policies and Procedures.***

What to submit to the Reviewing IRB:

Submit ALL activities to the Reviewing IRB, i.e. modifications, continuing reviews, adverse events, protocol deviations, other reportable events, and any other information as required by the Reviewing IRB.

What Modifications to submit to the Stanford IRB:

- Change in Protocol Director or other study personnel
- Change in Stanford required Consent language
- Addition of MRI procedures (when using the Lucas Center and/or CNI, Jordan Hall)
- Updating Protected Health Information (PHI) to be accessed or collected
- Any change that requires additional Stanford institutional and ancillary review

What to Report to the Stanford IRB:

- When the study is closed, terminated or suspended
- Any local protocol event that requires prompt reporting, including:
  - Possible Unanticipated Problem posing risks to subjects or others
  - Possible serious and/or continuing noncompliance
  - Unresolved participant complaints

Please consult with the Stanford IRB if you are uncertain whether your event should be submitted to both the Reviewing IRB and Stanford IRB.

Stanford reporting timelines should be followed for reports submitted to the Stanford IRB. The Reviewing IRB may have different reporting timelines and investigators must adhere to those timelines when submitting reports to the Reviewing IRB

LINKS

- eProtocol
- Stanford required consent form language
- Final NIH Policy on Single IRB
- Common Rule Cooperative Research