Purpose of Form: These guidelines are for study teams that have been asked to join a multi-site study as a "relying site" that will be reviewed by an external, single institutional review board (sIRB). This document may be customized to fit the needs of the site, study, and related ancillary reviews to maximize efficiency and accuracy.

Guidelines for Relying Site Study Teams: Enhancing sIRB Process Standardization

1. Readiness Assessment (Pre-sIRB Approval Work)

Follow these steps to evaluate whether your site meets the necessary criteria and is prepared to implement the study under the external sIRB's oversight.

A. *Review the essential study records (protocol, consent, etc.) from the lead site to ensure that the study is appropriate and feasible for your site.*

This review should be performed as you would when considering taking on any study at your site. Points to consider include, whether:

- You will be able to conduct the study per the protocol.
- You have adequate resources to conduct the study.
- The study meets your site's regulatory and compliance requirements.
- You will be able to meet recruitment and retention goals.
- You will have the financial resources to support the study.

B. *Obtain permission from your institution to use the external reviewing IRB designated to oversee the study.*

Many institutions have a process for providing permission to use an external reviewing IRB. Contact the human research protection program (HRPP) or other responsible office at your institution to determine whether they have such a process.

If your institution does not have an HRPP or a designated office for research oversight, identify the individual authorized to make decisions about human subjects research—this may be an institutional official, department head, or other organizational leader—and consult with them to determine whether such a process exists or is needed.

C. *Familiarize yourself with external reviewing IRB processes.*

1. Clarify key approval processes, including:
    a) How will the sIRB approve your site?
    b) What documents will be required from your site?

c) How will the sIRB approve the consent form at your site? Confirm that you can revise the consent form to include the required local information.

2. Ensure you understand how the sIRB will approve protocol modifications, including study-wide modifications and site-specific modifications
3. Identify the point of contact at the site for sIRB communications.
4. Determine who is responsible for identifying and managing COIs of investigators at your site.
5. Determine whether your site will have to pay for any part of the sIRB review process.

D. Ensure your site can meet its responsibilities when conducting a study overseen by a sIRB.

1. The principal investigator (PI) is responsible for the conduct of the research study at your institution. While the core responsibilities of the research team remain largely unchanged from when your local IRB oversees a study, the relying site study team will need to:
    a) Determine whether your site will have to follow your local IRB policies or the policies of the sIRB. You will likely have to follow at least some of the sIRB policies. You will need to review these policies to ensure that your site can comply with them.
        - It is important that you understand the Reviewing IRB's reportable event policy, to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events the Reviewing IRB requires to be reported within the required timeframes. The Reviewing IRB policy may differ from that of your local IRB.
        - Participating Institutions are strongly encouraged to use the SMART IRB Standard Operating Procedures (SOPs) for research covered under the SMART IRB Agreement.
        - When using the SMART IRB Agreement for a reliance arrangement, Participating Institutions may opt to use their own policies and procedures for the reliance relationship, if doing so would not render the Participating Institutions in violation of any term of the Agreement.
    b) Identify the information you must provide for your institution when an sIRB reviews a study. Do they want copies of approvals from the sIRB? Do reportable events need to be submitted to your local IRB?
2. See the following SMART IRB guidance for your responsibilities when relying on an external sIRB to oversee your study.
    - Study Team Roles Related to Single IRB

- Relying on an External IRB: FAQs for Research Teams
- Relying Investigator Guidance and Checklist
- Potential Relying Site Study Team Survey
- SMART IRB SOP Manual

2. Steps for Securing Approval from the External Reviewing IRB for your site (sIRB Approval Work)

These steps are for study teams that have the appropriate resources, departmental support, and HRPP support to be a relying site on a multi-site study overseen by an external sIRB. To ensure your site receives approval from the external sIRB, you will need to prepare necessary documentation, engage relevant stakeholders, and adhere to specific submission guidelines, as outlined below.

A. Work with your local HRPP to:

i. Submit the study according to local HRPP processes.

ii. Identify local ancillary reviews that must be completed before site activation.

iii. Identify institutional and local context information relevant to the study. (*See SMART IRB Guidance: Institutional Profile and PROTOCOL-SPECIFIC DOCUMENT To Collect Institutional Requirements from Relying Institutions*)

B. Work within your local study team to:

i. Identify study personnel and ensure that they have the training and qualifications to conduct the research and disclose relevant COIs.

ii. Complete Protocol Specific Document

1. Captures a relying institution's protocol-specific requirements
2. Documents how the IRB will review and approve the protocol for the relying institution

C. Work with the lead study team and local HRPP (if applicable) to:

i. Incorporate locally required language into the consent template. (*See Inserting "Local Context" Language in Informed Consent Documents*)

ii. Submit the required documents to the lead study team or coordinating center. These will vary depending on the site, sIRB, and study. The lead study team should advise on the next steps.

D. Document approval from sIRB. (i.e., approval letter).

3. **Steps for Securing Approval to activate the study at your site (Site Activation).**

   Ensure that all local ancillary reviews are completed before site activation. Do not begin the study until you complete all local activation processes and the lead site approves your site's activation.

4. **Study Implementation and Conduct–Steps for Maintaining Compliance (Post-IRB Approval Work)**

   1. Start up (Site Initiation Visit, contracts, etc.)
   2. Modifications (Do not initiate any study or changes of the protocol without approval from the Reviewing IRB, except those to eliminate an apparent immediate hazard.)
      - Personnel updates
      - Study-wide protocol modifications
      - Site-specific modifications
      - Consent modifications
   3. Continuing reviews
   4. Reportable events (noncompliance, unanticipated problems) may differ between sIRB and local IRB. Ensure you understand:
      - What the sIRB requires you to report to them, and when?
      - What your local IRB/institution requires you to report to them, and when?
      - What updates or events can trigger local IRB reviews, and when? (e.g., conflict of interest committee, billing compliance, HIPAA compliance). Recommendation: create a tracking tool to monitor and manage these events effectively.

5. **Study Completion – Steps for Site Close Out (IRB Closure Work)**

   1. Complete the study at your site (work with the lead study team to determine when all research is complete at your site and it may be closed by the sIRB).
   2. Follow the sIRB's instructions to prepare for site study closure.
   3. Submit final reports: Provide all final documents and data to the sIRB.
   4. Document approval of study closure at your site by the sIRB.
   5. Notify local HRPP of study closure.
   6. Store data: Ensure that all study data is securely stored as required by the lead site and regulations.

Glossary link: https://smartirb.org/glossary/