# Reviewing IRB Instructions for Relying Site Study Teams

**Purpose:** A Reviewing IRB may use this template to communicate key information to Relying Site Study Teams about the reliance arrangement and next steps after finalizing the arrangement.

This document presumes the Reviewing IRB uses the SMART IRB Standard Operating Procedures (SOPs) to govern the reliance arrangement, including study team roles. The SMART IRB SOPs require identification of a Lead Study Team that performs specific communication roles, such as submitting the initial review application and local amendments to the Reviewing IRB on behalf of Relying Site Study Teams and disseminating IRB notifications and IRB-approved documents to Relying Site Study Teams on behalf of the Reviewing IRB. If the Lead Study Team model will not be followed, adapt this information to reflect the appropriate roles and responsibilities of the study teams.

Your study team will be participating as a site in the [NAME OF STUDY]. [NAME OF REVIEWING IRB] will serve as the Reviewing IRB for this study using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement). This document covers the following steps:

1. Reviewing the communication plan
2. Identifying your study team responsibilities
3. Preparing for IRB approval
4. Reporting important information
5. Reviewing key policies of the Reviewing IRB

## Reviewing the Communication Plan

[NAME OF THE REVIEWING IRB INSTITUTION] will follow the [*SMART IRB SOPs*](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf). Consequently, a Lead Study Team has been identified for this study; the Lead Study Team will assume primary responsibility for communications with the Reviewing IRB and Relying Site Study Teams regarding this research. Key communication responsibilities related to the reliance arrangement are outlined in the [*Communication Plan*](https://smartirb.org/sites/default/files/Communications_Plan_Form.pdf) included as part of this packet.

The Lead Study Team Point of Contact (POC) for this study is:

|  |  |  |
| --- | --- | --- |
| NAME: XX | TELEPHONE: XX | EMAIL: XX |

Contact the Lead Study Team POC with any questions about how to obtain information about the IRB review or provide information to the Reviewing IRB.

Contact the [SMART IRB POC](https://smartirb.org/participating-institutions/) at your institution if you have questions about your obligations related to the reliance arrangement or processes your institution requires you to follow.

## Identifying Your Study Team Responsibilities

Relying Site Study Teams are required to comply with the Reviewing IRB’s requirements and determinations, applicable federal regulations, and all applicable state and local laws and local institutional requirements relating to the ceded research. For example, reviews and approvals by ancillary committees may be required before the study can be activated at your institution. If you have any questions about what local requirements may apply to your study, contact your local SMART IRB POC. These [*FAQs for Research Teams Relying on an External IRB*](https://smartirb.org/sites/default/files/Relying_on_an_External_IRB_FAQs_for_Study_Teams.pdf) provide general guidance about study team roles and responsibilities related to single IRB review.

## Preparing for IRB Approval

1. **Work with the Lead Study Team and the SMART IRB POC at your institution to provide:**
   1. [IF INFORMED CONSENT WILL BE REQUIRED, INCLUDE THIS SECTION] Consent Document(s); your study team will need to work with the SMART IRB POC at your institution to assure the study consent documents contain your institution’s or other acceptable language related to:

* Subject injury
* Any differences in study cost
* Local study team contact information

|  |
| --- |
| Note: Only modify the sections in the consent documents that the Reviewing IRB has indicated. |

* 1. Conflicts of Interest: Throughout the life of the study, each study team will need to ensure any applicable management plans for conflicts of interest relevant to ceded research are provided to the Lead Study Team to communicate to the Reviewing IRB.
  2. Human Subjects Training and Qualifications of Study Team Members: Your institution’s SMART IRB POC will need to provide confirmation to the Reviewing IRB that all of your study team members have met your institution’s requirements to perform the research.

1. **The Lead Study Team POC will contact Relying Site Study Teams to:** 
   1. Collect information on any variations in study procedures at the site, such as subject identification and recruitment; the Lead Study Team will then provide this information to the Reviewing IRB
   2. Communicate how it will disseminate IRB determinations and IRB-approved documents

## Reporting Important Information in a Timely Manner

Relying Site Study Teams will work with the Lead Study Team to submit the following to the Reviewing IRB:

1. All local changes of protocol
2. Information for any applicable continuing reviews for your site
3. Reportable events (e.g., noncompliance, unanticipated problems) that occur at your site and meet the Reviewing IRB’s requirements for reporting
4. Significant subject complaints that you receive (e.g., those that could affect the conduct of the ceded research)
5. Subject injuries that you are informed of related to the research
6. Personnel changes, as required by the Reviewing IRB; note: you may need to work with the SMART IRB POC at your site to obtain sign-off to ensure all staff have current training (as required by your institution) and are qualified to conduct the research
7. New or updated management plans for any potential financial conflicts of interests relevant to the ceded research
8. Closure report for your site

## Reviewing Key Policies of the Reviewing IRB

[NAME OF REVIEWING IRB INSTITUTION]’s policies must be followed regarding reportable events and personnel changes [INCLUDE ANY OTHER KEY POLICIES]. These policies may differ from those of your home institution. Relevant policies are identified below and [ARE ATTACHED TO THIS COMMUNICATION or ARE AVAILABLE AT:

* 1. UNANTICIPATED PROBLEMS [link to website]
  2. NONCOMPLIANCE [link to website]
  3. OTHER REPORTABLE EVENTS [link to website]
  4. PERSONNEL CHANGES [link to website]
  5. OTHER KEY POLICIES THAT COULD AFFECT THE RELIANCE ARRANGEMENT [link to website]]

Enc:

* Communication Plan
* [Relying on an External IRB: FAQs for Research Teams](https://smartirb.org/sites/default/files/Relying_on_an_External_IRB_FAQs_for_Study_Teams.pdf)