# Reviewing IRB Instructions for Relying Institution Point(s) of Contact

**Purpose:** A Reviewing IRB may use this template to communicate to Relying Institution Points of Contact (POCs) key information about the reliance arrangement as well as 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 the 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 site has been identified as a Participating Institution in the [NAME OF STUDY]. [NAME OF REVIEWING IRB] will serve as the Reviewing IRB for this study and will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to establish reliance between Participating Institutions and the [NAME OF THE REVIEWING IRB INSTITUTION]. This document covers the following steps:

1. Documenting the reliance arrangement and implementing the SMART IRB Agreement
2. Reviewing the communication plan
3. Providing information about local considerations to the Reviewing IRB
4. Ensuring compliance with Reviewing IRB policies
5. Ensuring the Relying Site Study Team provides the Reviewing IRB with timely reports
6. Complying with institutional reporting requirements

## Documenting the Reliance Arrangement and Implementing the SMART IRB Agreement

Use of the SMART IRB Agreement for this reliance arrangement [will be/has been documented through [SMART IRB’s Online Reliance System](mailto:https://reliance.smartirb.org/users/sign_in) OR is documented in the attached [*Letter of Acknowledgement*](https://smartirb.org/sites/default/files/Template_Letter_of_Acknowledgement.docx).] Also included in this packet is the [*Implementation Checklist for the use of the SMART IRB Agreement*](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf)*,* which documents how the [NAME OF REVIEWING IRB] plans to address the flexible components of the SMART IRB Agreement. If you have any questions or requests for changes to the Implementation Checklist, please contact [NAME OF PERSON/POSITION, such as the Reviewing IRB Point of Contact (POC)] as soon as possible.

## Reviewing the Communication Plan

[NAME OF 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 *Communication Plan* describes, for example, who is responsible for preparing and submitting the IRB application for each site to the Reviewing IRB.

Key individuals that can facilitate communication for this study are listed below.

The Lead Study Team POC for this study is:

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

The Reviewing IRB POC for this study at [NAME OF INSTITUTION] is:

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

If you have questions about the reliance arrangement or Reviewing IRB requirements, please contact the Reviewing IRB POC.

## Providing Information About Local Considerations to the Reviewing IRB

1. **The SMART IRB POC at your institution will be asked to provide the following to the Reviewing IRB:**
   1. Local Considerations; this information includes
      1. Any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews that are relevant to the ceded research study and that could affect the conduct or approval of the research at the Relying Institution.
      2. Any specific local requirements and restrictions on use and disclosure of Protected Health Information (PHI) that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization with respect to the Relying Institution.

This information will be collected by [identify method of information collection, e.g., via the SMART IRB [Institutional Profile](https://smartirb.org/sites/default/files/Institutional-Profile-20180726.pdf) and [Protocol-Specific Document](https://smartirb.org/sites/default/files/Protocol-Specific-20180726.pdf) or another method, such as Qualtrics or REDcap]. You may need to work with your local study team to provide the necessary protocol-specific local considerations.

* 1. [IF INFORMED CONSENT WILL BE REQUIRED, INCLUDE THIS SECTION] Consent Document(s); assure the study consent documents contain your institution’s or other acceptable language related to:
     1. Subject injury
     2. Any differences in study cost
     3. Local study team contact information

|  |
| --- |
| Note: Only modify the sections in the consent documents that the Reviewing IRB has indicated. If the Relying Institution has any other **required** informed consent language, please contact the Reviewing IRB POC listed above to discuss. |

* 1. Human Subjects Training and Qualifications of Study Team Members; provide confirmation that Relying Site Study Team members have met the Relying Institution’s requirements for human subjects training and are qualified to perform the research.
  2. Conflicts of Interest
     1. [UNLESS THE REVIEWING IRB HAS AGREED TO AN ALTERNATE PROCESS AS OUTLINED IN THE IMPLEMENTATION CHECKLIST, INCLUDE THE FOLLOWING] Confirm that the Relying Institution has conducted a review in accordance with its policy to determine whether any study team members have any significant financial interests relevant to the study. Ensure relevant management plans are communicated to the Reviewing IRB.
     2. Ensure your study team is aware that it is required to provide any applicable management plans for relevant conflicts of interest to the Lead Study Team to communicate to the Reviewing IRB throughout the life of the study.

1. **The Lead Study Team POC will** 
   1. Reach out to the Relying Site Study Team to collect information to identify any variations in study procedures at the site, such as subject identification and recruitment or other differences in implementation.
   2. Provide this information to the Reviewing IRB as part of the site’s IRB application.

The attached *Relying Site Study Team Instructions for Single IRB Review* will be sent to Relying Site Study Teams to provide guidance about next steps that are specific to them.

## Complying with Reviewing IRB Policies and Determinations

Relying Institutions are required to ensure compliance with the Reviewing IRB’s determinations and requirements. For this study, Relying Site Study Teams must follow [NAME OF REVIEWING IRB INSTITUTION]’s policies regarding [REPORTABLE EVENTS, PERSONNEL CHANGES, OR OTHER POLICIES]. These policies may differ from those of the Relying Institution. Relevant policies [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]]

## Ensuring the Site Study Team Provides the Reviewing IRB with Timely Information

Relying Institutions are responsible for ensuring their study teams are informed of and 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. After IRB approval, the Relying Institution is responsible for ensuring their study team works with the Lead Study Team to submit the following to the Reviewing IRB:

1. All local changes of protocol
2. Site information for any applicable continuing reviews
3. Reportable events (e.g., noncompliance, unanticipated problems) that occur at the local site and meet the Reviewing IRB’s requirements for reporting [Reviewing IRBs may wish to reference SMART IRB’s guidance, [*Reportable Events: Recommendations for Investigator-Initiated Multisite Studies*](https://smartirb.org/sites/default/files/Reportable_Events.pdf)]
4. Significant subject complaints (e.g., those that could affect the conduct of the ceded research)
5. Subject injuries related to the ceded research
6. Personnel changes, as required by the Reviewing IRB
7. New or updated management plans for any potential financial conflicts of interest relevant to the ceded research
8. Closure report for the site

## Complying with Institution Reporting Requirements

Under the SMART IRB Agreement, the Relying Institution is responsible for promptly communicating the following to the Reviewing IRB:

1. Any request to provide information pursuant to law or to legal process (e.g., a subpoena or a public records request) in connection with the ceded research, or knowledge of a threatened or actual claim, suit, or action arising from the ceded research)
2. Any suspension, restriction, termination, or expiration of its FWA; any failure to maintain registration of its IRB(s); or any loss of or change to its HRPP accreditation status or change to other HRPP quality assurance assessment that was the basis of the institution’s eligibility to join SMART IRB
3. Any specific local requirements and restrictions on use and disclosure of PHI that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization with respect to the Relying Institution
4. Any suspension or restriction by the Relying Institution (or any third parties) of any of its research personnel’s authority to conduct the ceded research

Enc:

* [IF APPLICABLE: Letter of Acknowledgement]
* Implementation Checklist for the use of the SMART IRB Agreement
* Communication Plan
* Relying Site Study Team Instructions for Single IRB Review