# Reviewing IRB Instructions for Relying Site Study Teams

Your study team will be participating as a site in the [NAME OF STUDY]. University of Michigan will serve as the Reviewing IRB for this study using the SMART IRB Agreement [or University of Michigan IRB-HSBS IRB Authorization 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

The University of Michigan (U-M) Health Sciences and Behavioral Sciences IRB (IRB-HSBS) will follow the [*SMART IRB SOPs*](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf). The U-M study team is the Lead Study Team for the project and 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/) [IRB Reliance Coordinator] 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 [or IRB Reliance Coordinator}. 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 U-M Study Team and the SMART IRB POC [or Reliance Agreement Coordinator] 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 [or Reliance Agreement Coordinator] at your institution to assure the study consent documents contain your institution’s or other acceptable language related to:
* Subject injury, if the research is more than minimal risk
* Any differences in study compensation
* Local study team contact information

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| 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 U-M Study Team to communicate to the Reviewing IRB.
	2. Human Subjects Training and Qualifications of Study Team Members: Your institution’s SMART IRB POC [or Reliance Agreement Coordinator] will need to confirm to the Reviewing IRB that all of your study team members have met your institution’s requirements to perform the research.
1. **The U-M 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 U-M 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 U-M Study Team to submit the following to the Reviewing IRB:

1. All local changes of protocol (rare)
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 (see attached Adverse Event and Other Reportable Information or Occurrences guidance)
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 are responsible for ensuring that 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

The U-M IRB-HSBS policies must be followed regarding reportable events and personnel changes. These policies may differ from those of your home institution. Relevant policies are attached:

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* U-M 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)