**Relying on an External IRB: FAQs for U-M Research Teams (IRB-HSBS Relying on an External IRB)**

The purpose of this document is to provide helpful hints for study teams when **IRB-HSBS** has agreed to rely on an external IRB.

***What does relying on an external IRB mean?***

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

***How do I know whether a study can be ceded to an external IRB?***

Please check with **Mary Donnelly (****mardonne@umich.edu****), sIRB Coordinator or** **irbhsbs@umich.edu** to find out:

* what research qualifies for ceded review
* how to make requests for ceding IRB review, and
* what, if any, agreement may be in place to cover the specific IRB review arrangement.

***Does U-M need to sign an agreement in order to rely on an external IRB?***

Generally, a written agreement between the institutions must be executed for an institution to rely on an external IRB. The agreement spells out the responsibilities of the institution providing IRB review as well as the institution relying on the external IRB.

***What is the SMART IRB agreement?***

The SMART IRB agreement is a national **master** **agreement** that allows institutions to avoid having to negotiate individual agreements per study or group of studies. The **University of Michigan** has signed onto the SMART IRB agreement. More information about SMART IRB is at <https://smartirb.org> and a list of institutions that have signed onto the agreement is at <https://smartirb.org/participating-institutions/>.

***Do I need to obtain sign-off from my home institution, such as its IRB office, to use an external IRB?***

Yes. Because institutions need to be able to identify the research that falls under its purview, even if an IRB outside the institution oversees some or all of its research. At the **University of Michigan, IRB-HSBS** researchers obtain sign-off to use an external IRB by completing a **Review by Non-UM IRB application (also known as a ceding application) in the eResearch system.**

***What is the role of my institution if research is ceded to an external IRB?***

Most reliance agreements, such as the SMART IRB Agreement, require institutions to communicate “local context” issues to the reviewing IRB. Local context issues can include institutional requirements for informed consent language, if appropriate, attesting to the adequacy of research team training, qualifications of the research team and resources available to conduct the study, and providing any relevant conflict of interest management plans. The IRB-HSBS will provide this Local Context information to the Reviewing IRB.

***How do I request my institution cede review for my study to an external IRB?***

Before submit a ceding application to the IRB-HSBS, contact the IRB-HSBS sIRB Coordinator via email or phone to discuss your plan.

Study teams need to provide the following information as part of the request to use an external IRB:

* Complete the Request for Reliance Agreement form. This includes information about the U-M PI, sponsorship (ePAF#), Reviewing Institution and FWA #, IRB Contact Person, Reviewing Site PI and contact information, and information regarding the U-M study team's activities in the research.
* Indicate whether the reviewing IRB is a participating SMART institution. Some institutions may require the use of the the SMART IRB Online Reliance System (<https://smartirb.org/reliance/>) to have study teams request reliance arrangements
* Provide the IRB-approved protocol and approval notice from the reviewing site.

***How do I submit my documents to the external IRB for review?***

* Each collaborating institution has its own policies and procedures regarding providing documentation to the reviewing IRB.
* Typically the study team at the reviewing site will be responsible for submitting documents to its IRB and provide you with documentation of that IRB’s approval for the conduct of research by U-M investigators.
* The IRB-HSBS will assist with communicating with the Reviewing IRB regarding the processing of the SMART or other reliance agreement.

***How do I know when I can start the research?***

The IRB-HSBS will issue an acknowledgement of the ceding application once the agreement process is complete, meaning that both the reviewing institution and U-M have signed the reliance agreement or acknowledged the SMART agreement and IRB-HSBS has received a copy of the final documentation.

The IRB must also have documentation the external IRB approval covers U-M's role in the research. If the external IRB has approved the study before your site is ready to join, your site will need to be specifically reviewed and approved as a new site, which is usually accomplished via an amendment to the existing study. Activities involving human subjects at your site cannot occur until the external IRB specifically approves your site’s participation in the research and you have obtained all required institutional sign-offs and/or approvals.

***What are my obligations when an external IRB is responsible for reviewing my research study?***

The responsibilities of the research team remain largely the same, and include:

* Submitting and obtaining acknowledgement of a "Review by non-UM" IRB application which is used to track reliance relationships with external IRBs
* Obtaining initial approval from the Reviewing IRB as a participating study site
* Communicating information about study progress and personnel updates (e.g., to confirm the study team is qualified and appropriately trained) to the Reviewing IRB via the mechanism established for such communications (e.g., either to the IRB directly or to the lead study team or to a coordinating center)
* Reporting unanticipated problems, noncompliance, and significant new information to the Reviewing IRB via the mechanism established for such communications
* Complying with the Reviewing IRB’s policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints)
* Complying with the determinations of the Reviewing IRB
* Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents
* Complying with applicable policies from the local institution (e.g., conflict of interest, training and education, research subject compensation processes)
* Where necessary, working with the lead study team to make any local updates to the protocol or other approved documents (e.g., consent form or recruitment materials) and ensuring the reviewing IRB approves these changes before they are implemented.
* Where U-M is involving in analysis of identifiable data only, ensuring that the appropriate data management and security procedures are in place for research data or specimens held at U-M.