Quick Guide: Single IRB (sIRB) and Reliance Agreements

What is Single IRB?

A Single IRB arrangement under NIH sIRB policy requires "that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States." sIRB" refers to the use of one IRB as lead reviewer for a U.S. based, HHS-funded, multi-site or cooperative agreement research. IRBs will either serve as the lead sIRB or deferring IRBs. All participating institutions must sign a reliance agreement with the lead site deferring IRB review responsibilities to the sIRB.

NOTE: UMass Lowell IRB will serve as the single IRB on multi-site studies on a case-by-case basis.

What Sponsors require the use of a Single IRB?

NIH Policy

As of January 25, 2018, the NIH has required the use of a Single IRB [sIRB] for the review of NIH-funded multisite studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. This Policy applies to domestic sites only. Under the policy, "multi-site" is defined as two or more sites.

For more information: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

Revised Common Rule

The Common Rule is a federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices. Under the new Final Rule governing human subjects protections approved by the DHHS in January 2017, most U.S. government funded cooperative studies that meet the criteria for non-exempt "human subjects research", and involve more than one site, will also require sIRB review. This requirement went into effect January 20, 2020.

For more information: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

What is a Reliance Agreement?

A reliance agreement is a written agreement that must be established when an institution engaged in research delegates institutional review board (IRB) review to an independent IRB or an IRB of another institution. Institutions may use different terms, e.g., reliance agreement or IRB authorization agreement (IAA). Reliance agreements may cover individual studies, categories of studies, or all human subjects research under an organization's Federalwide Assurance (FWA).

When is single IRB review required?

- Non-exempt human subjects research that is funded or supported by a federal agency and conducted in the US requires single IRB review (unless more than single IRB review is required by law, e.g., tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
- When single IRB review is required, the Federal department or agency supporting or conducting the research may determine and document that the use of a single IRB is not appropriate for the particular context. (https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html)
- Contact the UMass Lowell IRB before submitting a grant that involves a single IRB plan. A discussion is necessary to determine whether UMass Lowell is able to serve as the single IRB or rely on an external IRB.
- The UMass Lowell IRB will consider reliance agreements when sIRB is required and when sIRB is optional.

What if my research is Exempt?

Exempt studies are not subject to the sIRB mandate. The UML IRB may review Exempt studies itself or, if an external U.S. IRB generates an Exempt determination, the UML IRB may accept that external IRB's determination if it determines that the research meets Exempt criteria. The UML IRB relies on the materials submitted in the RES to make these decisions. Be sure to upload the outside IRB's determination in the "Attachments" section in RES. No reliance agreements will be signed for Exempt research.

What should a UML Investigator do when seeking reliance on an external IRB?

UML investigators who want UML IRB to rely on another institution's IRB should reach out first to IRB@uml.edu before submitting a protocol in RES.

What are my responsibilities as PI if UML agrees to rely on an external sIRB?

If the UML IRB agrees to the reliance arrangement, you as PI will need to ensure that study personnel receive appropriate training and are qualified to perform their duties, and that the study is conducted in accordance with the approved protocol and UML policies. You must notify the UML IRB of any changes to the study that could influence site specific requirements, such as, conflict of interest, study personnel, funding, consent forms (if applicable), notification of continuing review approval, reportable new information (e.g., adverse events), and closure of the study.

Does relying on an External sIRB mean there is no UML IRB review?

Not completely. The sIRB is responsible for conducting the ethical review and overseeing the non-exempt study at all sites, but each relying institution's IRB must ensure compliance with site specific state and local law, and institutional policy. That means that the UML IRB will conduct a "site specific" review to ensure that it is comfortable agreeing to rely on the sIRB, and that the study meets site specific requirements. The UML PI will have to meet sIRB requirements as well as site specific requirements imposed by the UML IRB.

What happens after UML IRB agrees to an External IRB?

Once you have received confirmation of UML's willingness to enter into a reliance arrangement, you may submit a new RES application. When submitting to RES, be ready to attachment the following materials:

- Documentation that the protocol has been reviewed and approved by the external IRB, (i.e. Approval Letter)
- IRB-approved protocol
- Documents provided by the external IRB for completion by the UML IRB (e.g. local context sheet, reliance agreement template, determination form, etc.)
- Consent form template approved by the sIRB (as applicable)
- HIPAA authorization, if applicable

The UML IRB will complete an administrative review of the external IRB application reviewing the application for local context concerns and completeness. The UML IRB staff will review the materials to ensure the following:

- The research is appropriate for submission to an external IRB and the PI meets the UML requirements to serve as PI on a research project.
- The application is complete and includes all required external IRB documents.
- The PI, co-investigators and key personnel have completed the required CITI human subjects training.
- All applicable ancillary review committees have completed and signed off on their reviews of the study.
- The Local Context form (if applicable) is complete and all required local context language is included in the consent form.
- For industry sponsored studies, the contract between UML and the sponsor of the research is finalized and the sponsor's commitment language regarding study related injury within the ICF has been verified.