SOUTHERN ILLINOIS UNIVERSITY
EDWARDSVILLE

Collaborative/Multi-Site Research

Definitions:

Multi-site project is one where the research will take place at multiple locations or institutions. It typically involves external collaborators/researchers.

Reviewing IRB (IRB of Record) – Conducts initial and continuing reviews, reviews amendments/modifications and unanticipated problems or adverse events that may arise. The reviewing IRB serves as the IRB of Record (also referred to as the single IRB or central IRB).

Relying IRB – The Relying IRB is the IRB that cedes review to the Reviewing IRB.

Institutional Authorization Agreement (IAA)– Also called Reliance Agreement – An agreement between two or more institutions engaged in the same human subjects research project that allows one or more institutions to cede review to another IRB. An IAA is required for non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

* SIUE will use an IAA for multi-site projects where the research is not exempt.

Individual Investigator Agreement (IIA) – Used when investigators are working on their own behalf or whose institution does not hold a Federalwide Assurance (FWA). The agreement provides a mechanism for which an institution with a FWA (like SIUE) may extend its FWA to cover the external investigator. The IIA outlines the responsibilities and expectations of the investigator while they are a part of the research project.

Question: When working with other researchers that are not affiliated with SIUE, do you complete an IRB protocol with SIUE?

Answer: Yes. If a SIUE faculty or student is an investigator in the study, then a protocol must be submitted to the SIUE IRB.

- **Exempt Multi-Site Projects Where SIUE Faculty/Staff/Student is the PI** – The submission process is almost exactly the same in this scenario as it would be if no external investigators were involved. The PI submits the protocol with all relevant information and attachments for IRB review and it is determined if the project meets the requirements for an exempt category of review. However, the PI must also include the names and information for any external researchers/investigators in the External Researchers section. All fields must be populated with the requested information (i.e., name, email address, institution, researcher role/experience/involvement and their human subjects training certificate). If any of the external institutions' IRBs have already reviewed the project, then their approvals should be included in the Attachments section of the protocol.

Once it is determined the project meets an exempt category and if no approval/determination information from the external institutions has been provided in the protocol, the IRB administration will contact the SIUE PI to:

- Tell all their external collaborators they must reach out to their home institutions and ask what their IRB offices will require them to submit for an exempt multi-site project.
- They must provide approval/determination letters from all institutions engaged in the collaborative research before the project can begin.

- **Exempt Multi-Site Projects where SIUE Faculty/Staff/Student is <u>not</u> the PI –** SIUE personnel are still required to obtain IRB approval prior to engaging in research. This includes multi-site or collaborative projects where SIUE personnel are co-investigators and not the PI. Similar to the process above, the SIUE personnel will submit the protocol for SIUE IRB review. The protocol should include:
  - Approved protocol from the initial reviewing institution
  - The approval letter from the initial institution
  - Any applicable documents that were approved (Informed Consent, recruitment materials, data collection instruments).

  The IRB administrator will review the submitted protocol and materials as a typical exempt protocol.

  ** In both scenarios above when the submitter believes the project to fall within an exempt category of review, they should select "Exempt Category Determination" in the Kuali Research protocol template when asked to indicate which type of review you are requesting from the IRB. See below for when to select "External Reliance."

- **Non-Exempt Multi-Site Projects when SIUE IRB is the Reviewing IRB –** Much like the process with exempt multi-site projects when SIUE personnel are the PI, the PI must first submit a protocol and include information about the external researchers and sites of investigation. If it's determined by the SIUE IRB to fall within expedited or full board review, an IAA will be drafted for each institution involved in the research. These will be sent to the relevant institutions for review and signature.

<u>Question</u>: How do I know when to fill out an External Reliance protocol?

<u>Answer</u>: SIUE personnel should submit an External Reliance protocol when the project is non-exempt, and the SIUE IRB will cede review to the external institution (reviewing IRB/IRB of record).

In many cases where the SIUE IRB is the relying institution, a request from the external IRB office will come directly to the IRB administrator to review the IAA. These agreements will be sent to the General Council for review and the IRB administrator will reach out to the SIUE PI to have them submit an external reliance protocol if they have not already done so.

The external reliance protocol submission must include a copy of the approved protocol from the Reviewing IRB with their approval letter and any applicable documents (informed consent, recruitment materials, surveys, interview questions, data collection sheets, etc.). Once the protocol is fully submitted and the IAA is signed by the relevant parties, the protocol is approved.

Question: If I'm working with a hospital with an IRB does that alter the SIUE IRB process?

Answer: Generally, it does not alter the process since the same federal human subject regulations apply. However, because IRBs can differ in their administrative processes, it is always advisable to reach out to the hospital IRB to find out what, if anything, they will require.