**Reliance Agreements with IRBs of Other Institutions**

**Updated March 13, 2022**

There are situations when Clark University researchers are involved in multi-site research or collaborative projects with investigators at other institutions. An IRB Authorization Agreement (IAA) is a special agreement between two institutions that are engaged in human subjects research to establish a Single IRB (or sIRB) with review authority. An IAA allows an institution with a Federalwide Assurance (FWA) to extend the applicability of its FWA to cover investigators at another institution. In practice, this means an institution’s IRB will be the IRB of Record which reviews the study. These agreements help to minimize regulatory burden on the IRB review and approval process by limiting the IRB review to one institution. When signing the IAA, one institution is designated the lead IRB or sIRB of Record. The IRB that relies on the review and oversight of another IRB is said to be “ceding” or delegating oversight to the lead IRB or sIRB.

Most research collaborations involving Clark University investigators fall into two models:

*Cooperative Research:* Cooperative studies involve investigators from two or more institutions working together to conduct a research project. Typically, participants are not enrolled at each site independently; instead one institution conducts the research interaction/intervention with participants and the other investigators/sites are involved in data analysis. Common projects of this type involve surveys, interviews or benign behavioral interventions, where researchers from multiple institutions collaborate to develop methods and/or analyze data for a research intervention/interaction for which one institution bears primary responsibility.

*Multi-Site Research:* Multi-site studies use the same research procedures outlined in a single protocol that is carried out at multiple institutions (e.g., a clinical trial where participants will be enrolled at each participating site independently, or an educational intervention implemented and overseen independently at each participating site).

**Single IRB Requirements for Federally Funded Research (sIRB)**

Effective January 20, 2020, most federally funded, non-Exempt cooperative or multi-site research must utilize an sIRB. An sIRB is the selected IRB of Record that conducts the ethical review for each site participating in the research. The sIRB allows multiple institutions that conduct the same protocol to cede to a single IRB for review. The sIRB requirement does not apply to international collaborations or where tribal or other laws require a separate IRB review for each collaborating site. Any Clark University investigator planning to conduct federally funded, non-Exempt cooperative or multi-site research should contact the IRB (humansubjects@clarku.edu) as early as possible to discuss alternatives for sIRB reviews. In some cases, these reviews may require investigators to obtain the services of commercial sIRB provider. Additional information is provided under *Which IRB should be the IRB of Record?*

**Which IRB should be the IRB of Record?**

Usually the institution of primary employment of the lead PI or the institution where most of the research is taking place will be the IRB of Record. The protocol should describe the specific procedures to be conducted at each research site, and the research personnel at each institution who will conduct those procedures. Each IRB may decide the appropriateness of ceding or accepting responsibility for the review of any research involving human subjects. The IAA must be approved and signed by the Institutional Officials at both institutions. Regardless of which IRB serves at the IRB of Record, the protection of participants in research projects remains the responsibility of all institutions and investigators involved in the research. Designating a reviewing IRB does not absolve another institution involved in the research of such responsibility.

In general, Clark University’s IRB *is* *equipped* to serve as the IRB of Record for *cooperative* research wherein a Clark University investigator is serving as the lead PI, and which involve procedures that the IRB reviews on a regular basis. Clark University’s IRB is *not equipped* to serve as the IRB of Record for cooperative research that involves procedures that the IRB does *not* review and approve on a regular basis (e.g., clinical drug or device trials).

Clark University’s IRB *is not generally equipped* to serve as the IRB of Record (or sIRB) for *multi-site* studies, whether or not a Clark University investigator is serving as the lead PI. Although Clark University’s IRB is currently not equipped to serve as the sIRB for multi-site studies, we will comply with the requirements for a participating IRB when another institution serves as the IRB of Record. Researchers should speak with the IRB office prior to submitting a proposal to a federal agency for a non-Exempt multi-site project. The IRB staff will assist PIs with identifying a suitable partner to act as the sIRB, including other institutions involved in the project or a commercial sIRB provider. Note that the investigator is responsible for any costs associated with the use of sIRB services by other institutions or commercial providers.

**Reliance Agreements (IRB Authorization Agreements)**

A reliance agreement, also known as an IRB Authorization Agreement, is a document
permitting one IRB (the “Relying IRB”) to cede review to another IRB (the “IRB of
Record”) for a particular study involving human participants. In some cases, an external
IRB will be the relying IRB and cede review to the Clark University IRB as the IRB of Record. In other cases, Clark University’s IRB will cede review to another institution’s IRB, allowing it to serve as the IRB of Record. For either case to occur, an agreement must be in place to delineate the roles and responsibilities of the involved parties. Most institutions with FWAs (including Clark) have standard IAA templates for these situations. The assurance signatory office (Dean of Research) at Clark is the designee to sign these documents. The Authorization Agreement (IAA) shall be completed and signed by both institutions.

**How Do I request that Clark University Serve as the IRB of Record?**

Before proceeding, review the types of research studies for which Clark University’s IRB is equipped to serve as the IRB of Record. As described above, Clark’s IRB is generally equipped to serve as the IRB of Record for collaborative research projects; it is not equipped to serve as sIRB for multi-site projects (see definitions above).

The following procedures should be followed:

1. The Clark Principal Investigator (PI) should contact the IRB (humansubjects@clarku.edu) for a preliminary conversation about the procedures that will be required and whether the IRB can serve as the IRB of Record.
2. Complete an application for the project using Mentor IRB (<https://www.axiommentor.com/login/shiblogin.cfm?i=clarku>). As part of your application form, make sure to identify all “external co-PIs” or other external participants in your study, and include their contact information.
3. As part of your Mentor application, clearly describe the participation and activities of all external research investigators, along with those of Clark investigators. Because you are requesting that Clark University serve as the IRB of Record, you must describe the activities of external investigators with the same level of detail given to activities of Clark Investigators.
4. Before electronically signing and submitting your protocol application in Mentor, use the “Messages” function in Mentor (click the link in the upper right corner) to notify the IRB that you are requesting that Clark’s IRB serve as the IRB of record for your collaborative project, and that you are requesting that an IAA be completed.
5. The IRB will inform you additional information is required before submitting your protocol. Once the protocol is submitted, it will be reviewed by the IRB following standard procedures for the type of protocol submitted.
6. If, after review and any required revisions, the protocol is approved or deemed Exempt, the IRB administrator will then communicate with you and the IRB of the collaborating intuition(s) to complete the required IAA and obtain signatures from the authorized organizational representatives. Once the IAA is completed, you will be provided with a signed copy by email. A copy will also be uploaded in Mentor.
7. Upon approval the executed IAA should be given to the collaborating intuition(s) along with the IRB Approval Letter.
8. If the protocol is denied (i.e., not approved or deemed Exempt) by the IRB, the researcher should communicate with the IRB to determine the reasons for denial, and (if appropriate) to prepare and submit a new protocol for review. The process then repeats beginning at Step 2.

**Training Requirements When Clark Serves as the IRB of Record**

The IRB’s policies and procedures require that all external investigators engaged in research at Clark (and at an institution with an FWA) complete whatever human subjects training is required by their home institution. Evidence of this training must be provided before the IAA is signed. Completion certificates must be attached in the personnel section of the IRB application in Mentor. See the separate policies and procedures document, *CITI Training Requirements* (updated February 12, 2021).

**How Do I request that Clark University Cede Review to Another IRB?**

The Clark PI must initiate a request for IRB reliance via email to humansubjects@clarku.edu. Once the IRB Administrator receives the request, the following steps are taken.

1. The Clark Principal Investigator (PI) should contact the IRB (humansubjects@clarku.edu) for a preliminary conversation about the procedures that will be required.
2. The IRB Administrator will communicate with them and the other IRB to determine (a) whether the protocol has been deemed Exempt, and (b) whether the other IRB is willing to serve as the IRB of Record (and sign an IAA).
3. If the other IRB is willing to serve as the IRB of Record, the IRB administrator will create a protocol in Mentor, selecting the “Delegate to other IRB” review type and waive all questions by selecting “Waiver Required Items for Submission” found at the bottom of the Action Form. The same procedure is used for Exempt and non-Exempt protocols.
4. As part of the application, the PI should upload the approval or Exempt designation letter provided by the other institution’s IRB, along with all application and supplementary materials provided to the other IRB. These should generally be uploaded as pdf files.
	1. The application materials approved or deemed Exempt by the other institution’s IRB *must* describe the participation of those at Clark University who will be engaged in the project.
5. The IRB administrator will then communicate with you and the IRB of the collaborating intuition(s) to complete the required IAA and obtain signatures from the authorized organizational representatives. Once the IAA is completed, you will be provided with a signed copy by email. A copy will also be uploaded in Mentor. Upon ratification of the IAA by both institutions, the other IRB becomes the sIRB of Record.
6. If the other IRB is NOT willing to serve as the IRB of Record because the protocol is Exempt, the following steps will be followed.
	1. The IRB Administrator will create an Exempt protocol for the PI in Mentor, manually upload all the other IRB’s approval/submission materials, and waive all questions by selecting “Waiver Required Items for Submission” found at the bottom of the Action Form.
	2. Waiving the questions is done *before* the protocol is “submitted”. This will allow the protocol to be submitted without answering the protocol application questions that would normally be required.
	3. The IRB Chair or designee reviews the submitted materials and will communicate with the PI to determine if any further application questions must be answered in Mentor to either approve the protocol or deem it Exempt.  The PI is required to complete those specific questions in Mentor, on a case-by-case basis.  In many cases, the protocol can be deemed Exempt based solely on the materials provided the other IRB.  If not, clarifications will be requested.
	4. The IRB will review the protocol and make an independent determination, following the same review procedures applicable to any independent submission.
7. If the other IRB is NOT willing to serve as the IRB of Record and the protocol was not deemed to be Exempt by the other IRB, then the PI must apply for separate and independent approval of the protocol in Mentor. (Note: If the study is funded by a federal agency, the **Single IRB Requirements for Federally Funded Research (sIRB)** may apply, as summarized above. If you have questions on this topic, please consult with the IRB for guidance.)

**Other Situations**

For any questions or situations that are not covered by the instructions above, please contact the IRB office at humansubjects@clarku.edu.