Guidance Document: IRB Authorization Agreement

Background

Every institution that conducts non-exempt human subject research files an assurance with DHHS. An assurance documents the institution's commitment to comply with HHS regulations for the protection of human subjects. This assurance is called the Federalwide Assurance (FWA). An institution's responsibilities under the FWA apply whenever the institution, its agents, or its employees are engaged in human subjects research, regardless of the geographic location of the research.

There are situations that arise when UMKC researchers are involved in multi-site research or collaborative projects with investigators at other institutions. Such research requires IRB review by each site engaged in the research unless an IRB Authorization Agreement (IAA) is in place. **An IAA is a joint review arrangement where one IRB relies upon the review of another qualified IRB to avoid duplication of effort.**

The IRB that performs the review is called the IRB of Record, the reviewing IRB, the lead IRB, and/or the primary IRB.

When is an IAA useful?

An IAA helps to reduce the burdens of multi-site research, which typically include multiple IRB applications for same project, multiple changes (sometimes conflicting) to secure approval, and multiple continuing review and amendment submissions.

The following examples are the most common situations where an IAA is used:

- UMKC acts solely as the funding recipient of an award and no research activities will be taking place at UMKC.
- The involvement of the UMKC investigators is limited to data analysis or other minimal risk, non-exempt activities.
- The other institution's reviewing IRB is more properly constituted to review a certain scope or topic of work, or may have knowledge of the local research context. (For example, an international research project where the interaction with subjects is performed at an external site and that site has an FWA.)
- The UMKC Investigator is involved in non-exempt research to be performed at another institution that either has or will have IRB approval.

When is an IAA not needed?

When UMKC, its agents, or its employees are **not engaged** in research, IRB review (and therefore an IAA) is not required. For example, if an investigator from another institution is conducting interviews on employees or students at UMKC without engaging any employees or student affiliated with UMKC, or collaboration with anyone affiliated with UMKC, then an IAA is not required.

In addition, an IAA is not appropriate for studies seeking exempt determinations.

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.

Protection of participants in research projects remains the responsibility of all institutions involved in the research. Designating a reviewing IRB does not absolve another institution involved in the research of such responsibility.

How do I request that UMKC cede review to another IRB?

1. The IRB Authorization Agreement is downloadable from IRB website. Download and complete the form and attach it to the submission.

2. The other documents attached to the submission should include:

    a. Approved version of the protocol – 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.
    b. Stamped or approved version of the consent form(s).
    c. Approval letter from the IRB of Record indicating the period of approval.

3. IRB staff will obtain the signature from the UMKC Institutional Official (IO). A copy of the IAA will be returned to you. Once the signatory official from the IRB of Record (Institution A) has signed the IAA and the research is approved, you should submit the completed IAA and documents approved by the IRB of Record.

4. If the study will continue following the original expiration date, the PI is required to submit the continuing review (CR) approval letter from the IRB of Record indicating the new approval period.

How do I request that UMKC act as the IRB of Record (i.e., UMKC accepts responsibility for the review)?

1. Follow the instructions on the IRB website for completing an Initial Application submission.
2. Include an IRB Authorization Agreement with your submission. Most institutions will have an IRB Authorization Agreement template to be used when relying on another IRB for review. If the institution you are working with does not have such a template, we suggest using the IRB Authorization Agreement from the UMKC IRB website.
3. Attach copies of your study documents as usual. In the protocol document describe the specific procedures to be conducted at each research site, and the research personal at each institution who will conduct those procedures.

4. IRB staff will obtain the signature from the UMKC IO. A copy of the IAA will be returned to you via eProtocol. The IAA will be active once both signatory officials have signed the IAA and the research is approved by the UMKC IRB. Upon approval the executed IAA should be given to the collaborating intuition(s) along with the IRB Approval Letter.