Background
Every institution that conducts non-exempt human subjects research files a Federalwide Assurance (FWA) with DHHS. The FWA documents the institution's commitment to comply with HHS regulations for the protection of human subjects. 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 Lehigh University 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 includes multiple IRB applications for the 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:

- Lehigh University acts solely as the funding recipient of an award and no human subjects research activities will be taking place at Lehigh University.
- The involvement of Lehigh University investigators is limited to analysis of data collected through the other institution 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 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 Lehigh University 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 Lehigh University, its agents, or its employees are **not engaged** in human subjects research, IRB review (and therefore an IAA) is not required. In addition, an IAA is not appropriate for research seeking or granted an exempt determination.

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 designated Human Subjects or IRB Signatory Official at each institution.

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 in the research of such responsibility.

How to request that Lehigh University's IRB cede review to another IRB

1. Complete and submit the "Request for Lehigh to Rely on External IRB" form through IRBNet.
2. Download and complete the "IRB Authorization Agreement – Other IRB of Record" form. The template is available on IRBNet. Attach the completed form to your IRBNet submission. The PI listed on the IRBNet application must be the PI listed on the IAA form.
3. Include the following documents within your submission in IRBNet:
    a. Approved version of the consent form(s).
    b. Approval letter from the external IRB of Record indicating the period of approval.
    c. Human Research Protection training certificates for all non-faculty personnel and for any faculty personnel who have not previously submitted training certificate to the IRB.
4. If the request to cede authority to another IRB is approved, the Lehigh University IRB Signatory Official will sign the IAA. A copy of the IAA will be returned to you via IRBNet. Once the Signatory Official from the IRB of Record (Institution A) has signed the IAA and the research is approved, you should submit the complete IAA and documents approved by the IRB of Record to Lehigh University through IRBNet. **Note: if the Lehigh University IRB does not approve a request to cede authority to another IRB, the IRB staff will consult with the Lehigh University PI to determine how to proceed with approval of the project.**
5. When the IRBNet submission has been submitted with all required documents, an IAA-Acknowledgement letter will be emailed to the PI. The expiration date listed on the letter and entered into IRBNet will be the date that is listed on the approval letter from the IRB of Record.
6. 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. This must be submitted in IRBNet as a Continuing Review submission. Lehigh University IRB staff will update IRBNet and a new IAA-Acknowledgement letter will be emailed to the PI.

How to request that Lehigh University act as the IRB of Record (i.e., Lehigh University IRB accepts responsibility for the review)

1. Submit a complete IRB application through IRBNet.
2. Include an IRB Authorization Agreement with your submission. Many institutions will have their own IRB Authorization Agreement template to be used when relying on another institution for IRB review. If the institution that you are working with does not have their own template, you may use the "IRB Authorization Agreement – Ceding to Lehigh University" template available on IRBNet. Before you submit the IAA, be sure you have filled out all fields.
3. Attach copies of your study documents to your IRBNet submission as usual. Describe the specific procedures to be conducted at each research site and the research personnel at each institution responsible for conducting those procedures.
4. If the request for the Lehigh University IRB to act as the IRB of Record is approved, the Lehigh University IRB Signatory Official will sign the IAA. A copy of the IAA will be returned to you via IRBNet. The IAA will be active once both signatory officials have signed the IAA and the research is approved by the Lehigh University IRB. Upon approval, the Lehigh University PI should provide the collaborating institution(s) with the fully executed IAA, along with the Lehigh University IRB approval letter. **Note: if the Lehigh University IRB does not approve a request to act as the IRB of Record, the IRB staff will consult with the Lehigh University PI to determine how to proceed with approval of the project.**