
An IAA is an agreement between two entities allowing the IRB of one entity to assume regulatory oversight for the other entity for a single or multiple research studies. When an IRB assumes regulatory oversight for another entity, it is referred to as the “designated” IRB. The entity accepting this IRB’s oversight is referred to as the “reliant” entity.

To request that Jefferson IRB serve as designated IRB:

- Submit an amendment (OHR-12) to add the new research site to the study. Indicate the local PI at the new site. Include proof of human subjects training for the local PI.

- Complete applicable fields on the IAA template and forward to the Office of Human Research (OHR) for signature. OHR will sign the form and forward to the appropriate official at the reliant entity for signature.

- Once fully executed, a copy of the IAA is provided to the PI, and copies are maintained in OHR and at the external entity.

- Once IAA is executed, reliant site may commence research activities.

To request that Jefferson rely on an external IRB:

- Provide the following to OHR via email (Portal submission not required):
  
  - Signed OHR-1 – pertinent to Jefferson personnel only
  
  - Copy of designated IRB approval letter
  
  - Copy of materials approved by designated IRB to be used with Jefferson research subjects (e.g., stamped consent form, surveys, diaries, etc.)
  
  - Copy of protocol & summary of specific duties of Jefferson personnel and procedures to occur at Jefferson
  
  - IAA template with applicable fields completed

- Create a record in JeffTrial

- Once fully executed, a copy of the IAA is provided to the PI, and copies are maintained in OHR and at the external entity.

- Once IAA is executed, Jefferson may commence research activities.

09/01/2015