Instructions for Requesting an IRB Reliance Agreement

An IRB reliance agreement (formerly known as an IRB authorization agreement) is an agreement between two entities allowing the IRB of one entity to assume regulatory oversight of research activities conducted at 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 or single IRB. The entity accepting this IRB’s oversight is referred to as the reliant entity or site.

If using Smart IRB to facilitate reliance agreement, please contact the Office of Human Research.

To request that Jefferson IRB serve as designated IRB:

- Submit all documents in the IRB Portal.

- For new study submissions, include the name of the reliant site and that site’s local PI on the OHR-1. Include proof of human subjects training for the local PI and study personnel. Also include local context questionnaire for the reliant site. (Available at https://www.jefferson.edu/university/human_research/forms.html under Miscellaneous Forms.)

- If site is being added subsequent to initial IRB approval, submit an amendment (OHR-12) to add the new research site and local PI to the study. Include proof of human subjects training for the local PI and study personnel.

- Complete applicable fields on the reliance agreement template and include with the new application or amendment. OHR will sign the form and return to the submitter, who should obtain signature from the reliant entity and return fully executed copy to OHR. The PI should also maintain copy in the study file.

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

- There may be additional requirements from the reliant site.

To request that Jefferson rely on Western IRB, Quorum IRB or Advarra IRB

- Check the website to see if the study meets criteria for using these IRBs: https://www.jefferson.edu/university/human_research/using-a-central-irb.html

- If criteria are met, submit OHR-1 in the IRB Portal.

- Following receipt of authorization document from Office of Human Research, proceed to submitting study to the commercial IRB via its electronic portal.
To request that Jefferson rely on any other external IRB:

- IRB must be AAHRPP-accredited
- Submit the following in the IRB Portal:
  - Signed OHR-1 – should include 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
  - Reliance agreement template with applicable fields completed
- Once fully executed, a copy of the agreement is provided to the PI, and copies are maintained in OHR and at the external entity.
- Once agreement is executed, Jefferson may commence research activities.