

Guidance for University of Kentucky Investigators: Requesting to Rely on an External IRB

Below are step-by-step instructions that University of Kentucky (UK) has established to help principal investigators (PIs) in completing IRB Authorization Agreements (IAAs) when requesting to rely on an external IRB.

*Please note: Although we have tried to simplify the process as much as possible, UK's E-IRB platform is limited in the streamlining process for ceding review, as the system was not originally designed with Single IRB and Reliance in mind.

1. In order for UK to agree to cede review and oversight to (or rely on) an external/reviewing IRB:
 - a. The UK PI completes a written request to defer IRB review to the external IRB using the Reliance Request/Registration Form which is available on the [UK ORI sIRB/Reliance Webpage](#).
 - b. The PI submits this form to irbreliance@uky.edu a determination as to whether the PI can cede review to an external IRB.
 - c. Once a determination is made for the UK PI to cede IRB review, the PI/study team creates an Abbreviated Application (AA) in UK's E-IRB system (contact Reliance Team for instructions on submitting AA).
Please note that before you can submit the abbreviated application in E-IRB, the PI and Department Chairperson signatures are required.
2. Reliance managers, UK IRB, and VPR, (and in some instances, ORI director and UK legal counsel) will review the protocol after the AA is submitted in E-IRB. Local ancillary reviews that may occur include:
 - a. HIPAA
 - b. Conflict of Interest
 - c. Institutional Biosafety Committee
 - d. Investigational Drug Service, and
 - e. Other state and local requirements (only if applicable).

3. If the PI/study team did not submit a consent form during initial E-IRB submission, the research may still be ceded to an external IRB; however, upon completion of the Consent/HIPAA combined form, the PI will need to:
 - a. submit a modification request to the E-IRB AA so that UK Reliance Team can review to ensure the documents meet all local/institution-specific requirements; and
 - b. ensure that the risk level documented in the AA matches the risk level determination of the reviewing IRB.
4. The IAA between UK and the external IRB will be submitted to the external IRB administrator for signature and returned to the UK Reliance Team, who will ensure the IAA is appropriately processed. Once the IAA and all supporting documentation are complete, these documents will be uploaded to E-IRB (and e-mailed to the PI/Regulatory Director, if that need is indicated).
5. Via e-mail, an E-IRB notification of the “Reliance Determination Letter” is issued, and includes confirmation that UK has agreed to cede review and oversight of the protocol. Additional instructions and document links will be included in this letter. This determination letter and the IAA can be downloaded from E-IRB and forwarded to any parties who need this documentation.
6. Once you receive the reviewing IRB’s approval letter for activation of UK’s site to participate in the proposed research, please modify the AA by attaching the letter to your currently approved AA in E-IRB and sending on for “review and approval” by UK’s Reliance Team.