Office of Research Integrity

Frequently Asked Questions (FAQ) Regarding the University of Kentucky Institutional Review Board (IRB)

What activities need IRB Review?

Research activities with human subjects, including surveys, record reviews, outcomes research, and clinical trials, require IRB review and approval. The Office of Research Integrity (ORI) has a guidance table that will tell you what activities do and do not need IRB review based on federal definitions and UK policy. Still unsure? Either call us or complete the "Not Human Research Determination Form" and email the form to us for an official ruling that can be provided to you on letterhead. These resources and more are available on the "*What Needs IRB Review*" website (www.research.uky.edu/office-research-integrity/what-needs-irb-review).

## Which type of IRB Review will my Protocol require?

The "*IRB Review Types*" website (www.research.uky.edu/office-research-integrity/irb-review-types) describes each type of IRB review and offers "*Issues to be Addressed*" guidance to help you decide if your protocol might be eligible for exempt or expedited review. Contact information for ORI Professionals who work with both the Medical and Nonmedical IRBs are listed for additional questions.

What type of training is required to conduct human research?

The IRB requires all study personnel to complete human subject protection (HSP) training every three years. If you have documentation of current HSP training, submit it to ORI for credit. UK HSP training is available on the "*Collaborative Institutional Training Initiative (CITI)*" website. UK employees and students must use their UK Link Blue ID and password and access CITI by clicking the CITI Button on the "*UK Link Blue*" website (www.uky.edu/see/page/linkblue-subpage).

Do I submit to the Medical or Nonmedical IRB?
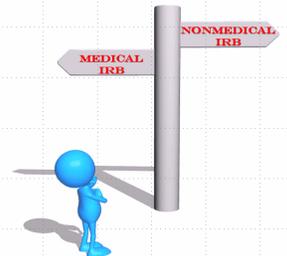
UK has four Medical and one Nonmedical IRB. The Medical IRBs review research from the Colleges of Dentistry, Health Sciences, Medicine, Nursing, Pharmacy and Health Sciences, and Public Health. The Nonmedical IRB reviews research from the Colleges of Agriculture, Arts & Sciences, Business & Economics, Communications & Information Studies, Design, Education, Engineering, Fine Arts, Law, and Social Work. (www.research.uky.edu/office-research-integrity/which-institutional-review-board-irb-will-review-my-research)

Does the IRB make exceptions to the requirement for local review?

While the current policy requires local review, request for exceptions may be submitted for consideration in cases such as sponsor-mandated use of an external IRB for multi-site research. See the Single IRB Reliance page for details (www.research.uky.edu/office-research-integrity/single-irb-reliance). Requests are reviewed by ORI, with input from legal counsel and/or the IRB. The Vice President for Research makes the final determination. Submit the IRB Reliance Request/Registration Form with Department Chair's signature to Jessica Williams, ORI Reliance Manager

Where do I submit protocols and what is the submission process?

Create and submit applications on E-IRB at ris.uky.edu/irb/DashBoard/login.aspx. UK employees and students must use their UK Link Blue ID and password to access E-IRB. Here researchers will find the application process, where they will be able to provide the necessary information for submission. Meeting dates are listed on the ORI website. The principal investigator attends convened IRB meetings. Sample IRB Application Materials and Protocol Templates are available at www.research.uky.edu/office-research-integrity/sample-applications-and-protocol-development-resources.

How do I transfer human research from my former institution or work with non-UK researchers or at non-UK facilities?
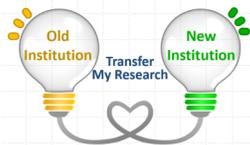
Contact ORI for assistance on how to transfer research to UK. Different requirements may apply depending on the stage of the research. When working with collaborators from other institutions or at non-UK facilities, ORI has procedures to work out any necessary collaborative agreements between investigators or IRBs. Refer to the Reliance website (https://www.research.uky.edu/office-research-integrity/single-irb-reliance)for contacts.

What are my responsibilities as a faculty advisor?

As a student's faculty advisor, you accept a supervisory role in guiding the student in conducting regulatory compliant research. You must be certified in HSP training. You will sign the protocol assurance statement certifying that you have reviewed the research and attest to the scientific merit of the study, qualifications of the personnel, and adequacy of the facility and resources needed to conduct the research. For full review protocols, you are encouraged to accompany the student to the IRB meeting. Staying apprised regarding requested revisions can enhance your IRB knowledge base for the benefit of current and future students.

What are my responsibilities as a principal investigator?

A principal investigator (PI) is ultimately responsible for all aspects of human research conduct. General investigator responsibilities are outlined in the "*Principal Investigator's Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research*". Detailed 'how to' guidance is provided in the "*Principal Investigator Q & A Guide*". Recruitment requirements are outlined in the "*PI Guide to Identification and Recruitment of Human Subjects for Research*". PIs who initiate FDA regulated research also must comply with sponsor regulatory requirements outlined in summary documents and mandatory sponsor-investigator training.

## How do I find out if FDA regulations apply to my protocol?

The IRB Drug and Device section of the IRB application, ORI guidance documents, and FDA website can help in determining if and which regulations apply. For assistance or to identify the best FDA resource, contact the ORI Research Education Specialist Belinda Smith at 859-323-2446 or belinda.smith@uky.edu.

Where do I find resources, procedures, and guidance?

See the Getting Started website for guidance and resources to navigate the IRB submission and review process (www.research.uky.edu/office-research-integrity/getting-started). See the IRB Survival Handbook for topical guidance documents and more (www.research.uky.edu/office-research-integrity/irb-survival-handbook). Announcements, events, and newsletters will be distributed on the IRB list serve and posted on the "*What's New*" website (www.research.uky.edu/office-research-integrity/news-announcements). Also see the Training & Education page for information on mandatory training, workshops and conferences (www.research.uky.edu/office-research-integrity/training-education). To be added to IRB email distribution lists, contact Jennifer Hill at jen.hill@uky.edu or 859– 257-2978.

Whom do I contact with concerns, suggestions, or questions?
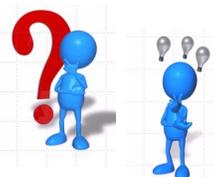
If the issue is regarding ORI or administrative procedures, contact ORI Director, Dr. Helene Lake-Bullock. For IRB determination issues, contact the applicable IRB Chair. The full ORI staff directory is available at www.research.uky.edu/office-research-integrity/contact-us. Submit feedback anonymously on ORI's customer service form (redcap.uky.edu/redcap/surveys/?s=jB2Nfm).