What activities need IRB review?
Research activities with human subjects require IRB review and approval. This includes surveys, record reviews, outcomes research, clinical trials, and more. 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. Or check out our short video for an overview of what needs IRB review. Complete and submit the Not Human Research Determination Form for an official ruling provided on ORI letterhead. These resources and more are available on the What Needs IRB Review webpage.

Which type of IRB Review will my protocol require?
The IRB Review Types page describes each type of IRB review and offers tools and guidance to help you decide which type of review applies to your study. If you plan to conduct research with material originally collected for another purpose, see the Secondary Use Tool for guidance.

What type of training is required by the IRB and University to conduct research?
The IRB requires all human research protocol study personnel to complete human subject protection (HSP) training every three years. If you have documentation of current HSP training through another institution, submit it to ORI for credit. UK HSP training is available through the Collaborative Institutional Training Initiative (CITI). UK employees and students must use their UK Link Blue ID and password and access CITI by clicking UK CITI Access on the Training & Education webpage.

UK now mandates that all faculty, staff, and students who conduct research must complete the Responsible Conduct of Research (RCR) training annually. If you have documentation of current RCR training through another institution, submit it to RCR@uky.edu for consideration. UK RCR training is available through CITI. For more information, please go to the Responsible Conduct of Research & Scholarly Activity (RCR) website.

Do I submit to the Medical or Nonmedical IRB?
UK has four Medical boards and one Nonmedical board. 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. See the webpage “Which Institutional Review Board (IRB) will review my research?” for more information.

Does the IRB make exceptions to the requirement for review by the UK IRB?
While the current policy requires UK IRB 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 webpage for details. Submit the IRB Reliance Request/Registration Form with Department Chair’s signature to the ORI Reliance Team at IRBReliance@uky.edu. Requests are reviewed by ORI, with input from legal counsel and/or the IRB. The Vice President for Research makes the final determination.

Updated 08/17/21
How do I transfer my human research from my former institution or work with non-UK researchers/facilities?

Contact ORI for assistance on how to transfer active 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 Single IRB Reliance webpage for contact.

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

Create and submit applications in E-IRB. 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. The Medical or Non-Medical IRB submission prep checklist will help you navigate the application. Meeting dates are listed on the ORI website. The principal investigator attends convened IRB meetings. Sample IRB Application Materials and Protocol Templates are available as well. For help with different E-IRB processes, please see the E-IRB Video Tutorial Library.

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 and RCR 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. Keeping an eye on requested revisions can enhance your IRB knowledge for the benefit of current and future students. See the ORI video training “Faculty Advisor Responsibilities” which includes ORI tools to help your students succeed with human subject research.

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 “PI Responsibilities Guide”. Detailed ‘how to’ guidance is provided in the “Principal Investigator Q & A Guide”. Recruitment requirements are outlined in the “PI Recruitment Guide”. For medical research, see the “Investigator Qualifications and Provision of Medical Oversight” guidance. PIs who initiate FDA regulated research also must comply with sponsor regulatory requirements outlined in summary documents and mandatory sponsor-investigator training. See our Researchers webpage for more tools.

How do I determine if FDA regulations apply to my protocol?

The IRB Drug and Device section of the IRB application and the Survival Handbook provide guidance for a variety of FDA-regulated research. The ORI Interactive Medical Device Trials and Drugs/Biologics Trials Flow Charts can help in determining if and which regulations apply. For assistance 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. See the [IRB Survival Handbook](#) for topical guidance documents and more. Announcements, events, and newsletters will be distributed on the IRB listserv and posted on the [News & Announcements webpage](#). Also see the [Training & Education webpage](#) for information on mandatory training, workshops and conferences. To be added to ORI/IRB email distribution list, complete the [subscription form](#).

What if I have concerns, suggestions, or questions?

For IRB determination issues, contact the applicable IRB Committee. Go to the [Contact Us webpage](#) to contact a specific staff member or submit feedback anonymously on our [customer service form](#). If the issue is regarding ORI or administrative procedures, contact ORI Director, [Dr. Helene Lake-Bullock](#).

You can also request a consultation if you aren’t sure who to ask. Consultations are offered for studies in development as well as approved research projects. Provide the E-IRB protocol number for approved or submitted studies. Click [here](#) to submit a request for consult.

We host Office Hours events as well, for your convenience. You’re welcome to drop in with any questions about current research, developing projects, the E-IRB system, and more! A variety of staff will be available to answer questions and provide support in real time. View upcoming dates [here](#).