Frequently Asked Questions on Mandatory Human Subject Protections Training

The Office of Research Integrity (ORI) has developed a new Mandatory Training website to aid study personnel in obtaining and maintaining Human Subject Protection (HSP) training as well as several other trainings that are protocol-specific or required by a specific funding agency. Experienced study personnel will find a direct link to the Collaborative IRB Training Initiative (CITI) online program on the ORI Home Page and at the top of the new Mandatory Training FAQ Page.

In addition to training requirements, information is available on CITI user functions such as recalling your password, combining multiple accounts, or printing previously completed course certificates. Course enrollment instructions include screenshots of the recently updated CITI website. The site includes a table of courses offered on CITI as well as an HSP course description for use in grant submissions. Contact information is provided for additional questions or special requests such as determining if a training completed at a different institution would meet the UK HSP training requirement.

The FAQs are grouped in the following categories to facilitate quick access to the needed information:

- Initial IRB Training Requirement: Who, What, When
- Initial CITI HSP Training for IRB Approval
- Three Year Refresher HSP Training
- CITI User Information
- Sponsor-Investigator CITI Training
- New Study Personnel and Continuing Review
- Non-UK or Community Based Study Personnel
- Contacts for training information or technical assistance
- Responsible Conduct in Research (RCR) Training
- Other protocol-specific education requirements

If your students need help navigating the IRB process, the Office of Research Integrity may be available to present to your class or group. Contact Belinda Smith, (belinda.smith@uky.edu; 859-323-2446), with questions and to determine availability.
CHANGES TO “OFF-SITE” RESEARCH REQUIREMENTS FOR IRB APPLICATION

Based on feedback from the University community, the Office of Research Integrity has made a change to the IRB application form when you are collaborating with non-UK sites or personnel. In order to simplify this process for investigators, we have integrated the questions that were previously addressed on “Form N: Off-Site Research” into other sections of the IRB application. The new forms are available as of September 1st.

Investigators should be aware, however, that the basic federal requirements for IRB review of all sites and personnel who are engaged in human subjects research have not changed. The following questions will still need to be addressed within your IRB application:

- Have you listed all of the locations where the research will take place, and whether or not those sites and/or their personnel are engaged in the conduct of human subjects research?
- Do the non-UK sites have their own Federalwide Assurance (FWA), or do they need to apply for one?
- Do you have a letter of support assessing the appropriateness of the research for the local context from each participating site?
- Is an IRB Authorization Agreement or Individual Investigator Agreement needed?
- If UK is the prime site, how is the PI ensuring oversight of the research activities at all locations?
- Is a consultant who has expertise in the culture and language of the off-site location needed?

If you have questions about conducting human subjects research with non-UK sites and personnel, please contact the following individuals in ORI for assistance:

Amy Kolasa, Off-Site Research Coordinator/ Medical Full Review protocols, (859) 257-9425;
Joanne Hines, Medical Expedited protocols, (859) 257-7467; or
Andrew Hedrick, Non-Medical Full and Expedited protocols, (859) 257-1639.