

University of Kentucky Sponsor-Investigator Mandatory Training

The IRB must ensure investigators who assume sponsor functions are knowledgeable about the regulatory and institutional requirements this entails. If you are functioning as the Principal Investigator (PI) and sponsor for a Food and Drug Administration (FDA) regulated product (drug, device or biologic), IRB policy requires that you successfully complete a one-time mandatory training. A sponsor-investigator must complete the applicable ORI web based training before final IRB approval is granted.

The training consists of a web-based course available through the University of Kentucky curriculum on the [Collaborative Institutional Training Initiative \(CITI\)](#).

Choose version (drug or device) applicable to research.

- Drug Development for Sponsor-Investigators
- Device Development for Sponsor-Investigators

These courses provide information on conducting investigator initiated studies according to FDA regulations and Good Clinical Practice (GCP) guidelines applicable to both investigators and sponsors of Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications.

If you have an account on CITI but do not recall your user name or password click the [Forgot login information](#) link on the CITI homepage at www.citiprogram.org. Access the applicable course by clicking **i Add a course or update your learner groups for University of Kentucky** on the **Main Menu**. Instructions on setting up an account is available for new CITI users http://www.research.uky.edu/ori/ORIForms/42-CITI_instructions.pdf.

The Office of Research Integrity (ORI) will receive email notification of your successful completion of the course. Contact Belinda Smith, ORI Research Education Specialist, at 859-323-2446 or belinda.smith@uky.edu with question.

If you have documentation of completion of equivalent training please submit with your protocol application for the IRB's consideration as described in item 21 of the IRB Form B, Research Description.

In addition to this course, you may request or the IRB may suggest an individual consultation with the IRB chair or Education Specialist regarding your FDA regulated protocol.

CITI Collaborative Institutional Training Initiative

[Resources](#) [Main Menu](#) | [Select Language](#) | [Logoff](#)

Select Curriculum - University of Kentucky

Please make a selection below to view the available courses:

Choose one answer

IRB
Human Subject Protection (HSP) Training lists courses available to meet the Institutional Review Board (IRB) training mandate at the University of Kentucky (English and Spanish)

RCR
Responsible Conduct of Research (RCR) Training- lists RCR training options for various discipline or areas of research. Covers topics such as research misconduct, conflict of interest, mentoring, collaborative science, responsible authorship, etc. Required for some academic programs, grants, or funding opportunities. *[RCR training does not meet the IRB training mandate]*

Choose one answer

- Initial Human Subject Protection (HSP) Training lists options available to meet the initial Institutional Review Board (IRB) training mandate at the University of Kentucky (English and Spanish)
Contact the Office of Research Integrity (ORI) at 859-257-9428 with questions.
- Refresher Human Subject Protection (HSP) Training lists HSP refresher options available to meet the three (3) year IRB re-certification requirement. You must have completed the Initial Human Subject Protection Training in order to complete the refresher training.
Contact the Office of Research Integrity (ORI) at 859-257-9428 with questions.

or

- Drug Development for Sponsor-Investigators (good clinical practice (GCP) course required for sponsor-investigators of investigational drug trials).
- Device Development for Sponsor-Investigators (good clinical practice (GCP) course required for sponsor-investigators of investigational device trials).
- Optional Courses additional courses of interest including HIPAA and Good Clinical Practice (GCP). (English and Spanish)

FAQ

Is this training required for all types of investigator-initiated research?

No, not all types. [It is required](#) for PIs conducting investigator-initiated research with a FDA regulated product (drug, device, biologic), where the PI is also acting as the “sponsor” of the research. This includes research where the PI holds the Investigational New Drug (IND) or Investigational Device Exemption application with FDA, as well as non-significant risk device trials which require compliance with FDA abbreviated regulatory requirements.

Is this required if the PI is a sponsor-investigator of a non-significant risk device study in which an IDE application is not required? Yes. As itemized in the [ORI documents summarizing](#) FDA requirements for PIs who are considered sponsors, sponsor-investigators of non-significant device studies have abbreviated sponsor responsibilities.

Is the PI required to complete both the drug and device course? If the PI has plans to sponsor drug and device investigator initiated studies in the future, he/she may choose to complete both. Otherwise he/she may complete only the applicable course and exam (drug or device). If the PI is serving as the sponsor-investigator for a combination drug and device study then he/she should complete both the drug and device course.

Are there requirements to repeat the sponsor-investigator training? No, this is a one-time training requirement.

Is this training required for PIs conducting studies that are investigator-initiated, where the only involvement of a commercial sponsor is to provide the investigational product?
Yes, particularly if the clinical trial agreement designates the PI as the “sponsor” from an FDA perspective.

What if the decision as to whom will act as the “sponsor” has not yet been determined?

Proceed with your IRB application and simply indicate that **if** the PI is given sponsor status, he/she will take the applicable training. Contact the IRB once the decision has been made.

Are sub-investigators or other personnel required to complete the sponsor-investigator training?

Unless specifically requested by the IRB, the training is only required for the PI acting in the “sponsor” capacity. Ensuring compliance of all participating investigators and research personnel is already a sponsor function. In addition, FDA has issued [guidance](#) on their expectations regarding supervision and task delegation. A sponsor-investigator may choose to require any individual acting on their behalf or in their absence to complete the training.

If I completed the previous Sponsor-Investigator course on Blackboard do I need to repeat one of these courses?

No. Unless specifically required by the IRB on a protocol specific basis, this is a one-time training requirement. Completion would be optional but strongly encouraged if you took drug specific training and now are serving as a sponsor-investigator for a device study (or vice versa). Contact ORI at 323-2446 to confirm what previous trainings you have on file.

Additional resources are available under Drug and Device tabs of the ORI Survival Handbook located at <http://www.research.uky.edu/ori/IRB-Survival-Handbook.html>