

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 complete a one-time mandatory training.

The didactic portion of the training consists of completion of the applicable portion of the Office of Research Integrity Blackboard Course *ORI000-NC: Sponsor-Investigator Clinical Trials with FDA Regulated Products*. You may log into Blackboard using your active directory account (the same account you use for Exchange email), enter the course number in the [course search](#) field and [self enroll](#). Once you have reviewed the applicable modules (drug, device or both) and completed the associated course exam (drug, device or combination), contact the ORI Research Education Specialist at 859-323-2446 to obtain a certificate of completion.

A sponsor-investigator must complete the applicable ORI web based training before final IRB approval is granted. 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 require an individual consultation with the IRB chair regarding your FDA regulated protocol.

ORI000-NC COURSE OUTLINE	Required for sponsor- investigators of Investigational Drug Research	Required for sponsor- investigators of Investigational Device Research	Required for sponsor- investigators of Combination Research	Optional modules
Introduction	X	X	X	
Module 1- Regulatory Requirements & Overview of Responsibilities	X	X	X	
Protocol Development				X
Module 2- Drug Development & IND Submission	X		X	
Principal Investigator Qualifications & Responsibilities				X
Module 3- Regulatory Drug Responsibilities	X		X	
Module 4- Device Development & IDE Submission		X	X	
Module 5- Regulatory Device Responsibilities		X	X	
Comparison Chart & Combination Products			X	
Exam –Drug Research	X			
Exam –Device Research		X		
Exam –Combination Research			X	

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.

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

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

Will completion of the drug modules and exam suffice for sponsoring device trials and vice versa?

No. While some responsibilities are common to either FDA regulated product, there are product specific development routes, regulations and responsibilities necessitating completion of the applicable module and exam.

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 a commercial sponsor allows the PI to “cross-reference” their investigator-initiated protocol with an existing IND/IDE?

If the commercial sponsor retains all of the responsibilities of the “sponsor” from the FDA perspective, (i.e. investigator selection, data and study monitoring, FDA reporting, etc), then the PI would not be required to complete the training.

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.

If the PI completes the sponsor-investigator web based training will he/she still require consultation or one-on-one training with the IRB chair that was initially required for sponsor-investigators?

No, for the majority of cases the web-based training will be adequate. Answers to item 21 on the research description should provide the IRB with the information to make that assessment. The IRB could request a one on one consultation for a unique case or novel protocol that has requirements beyond the standard sponsor responsibilities, but this would be a rare case. In addition, the PI is welcome to request consultation with ORI or the IRB chair.

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 [draft 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.