Sponsor-Investigator Training now on CITI

Investigator initiated, FDA regulated protocols are held to the same standards and regulations imposed on industry sponsored research. Investigators who also assume the “sponsor” role take on additional regulatory, monitoring, and reporting responsibilities.

The Medical IRB is charged with providing training to ensure investigators are knowledgeable about the additional role they assume when serving as a sponsor-investigator. In the past, mandatory training was provided via an internally developed course housed on UK’s Blackboard website.

We are pleased to announce that new nationally developed courses are now available on UK’s curriculum via the Collaborative Institutional Training Initiative (CITI). Most human researchers are already familiar with and have accessed CITI for completion of Human Subject Protection training.

The new 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.

Depending on the type of protocol, sponsor-investigators may choose Drug Development for Sponsor-Investigators or Device Development for Sponsor-Investigators. While completion is mandatory for new sponsor - investigators, others involved in the conduct of FDA regulated trials will find the regulatory reminders and practical guidance beneficial.

The Office of Research Integrity (ORI) will receive email notifications of those who successfully complete the course.

Instructions and frequently asked questions regarding the IRB training mandate and courses are described in the University of Kentucky Sponsor-Investigator Mandatory Training document. For additional questions or assistance, contact Belinda Smith, ORI Research Education Specialist, at 859-323-2446 or belinda.smith@uky.edu.
Department of Defense (DoD) Supported Research

Research that has at least portion of the funding, personnel, faculties, or other resources from the DoD is subject to additional DoD regulatory requirements designed to manage risks and ethical considerations unique to military or civilian DoD personnel.

For example an independent research monitor is required for greater than minimal risk research; safeguards are required to ensure autonomy when recruiting military or DoD employees; there are limitations on subject compensation; and other strategies that are population specific.

General requirements based on the November 2011 DoD Directive are outlined in the IRB Department of Defense SOP. In addition, the ORI and IRB use the following DoD guidance documents when reviewing DoD supported research:
- Summary of Requirements for DoD supported research
- DoD Checklist for IRB review

Research supported by a DoD Component, (Army, Navy, etc.) may involve additional requirements specific to that branch of the military.

It is important for the Principal Investigator (PI) to inform ORI and the IRB of any unique, Component-specific requirements outlined in early communications between the PI and the DoD sponsor.

Typically the human research protection officer (HRPO) within the sponsoring DoD Component performs an administrative review of the IRB approval and other submitted documentation to confirm compliance with Federal and DoD requirements.

2012 Human Research Protection Regional Conference
Friday, October 5, 2012
Northern Kentucky Convention Center

“Human Subject Protection: With A Little Help From Our Friends”

The 2012 conference will feature a diverse group of speakers discussing cutting edge topics such as:
- Social media in research
- Ethical relativism and its impact on research
- Returning genetic research results to subjects
- FDA’s oversight of human subject protection.

Additionally, this year’s key note speaker is Seth Mnookin, author of the New York Times best seller, *The Panic Virus: The Story Behind the Vaccine-Autism Controversy*. Seth will discuss his book and strategies to combat the growing public health crisis resulting from infants not being vaccinated.

Continuing education credits and nursing credits are also available to attendees. Attendance also counts towards renewal human subject protection training for UK researchers.

Co-sponsored by Schulman Associates IRB, Cincinnati Children’s Hospital Medical Center, the University of Cincinnati and the University of Kentucky, our 2012 conference promises to be another engaging and informative event for members of the research community.

Registration information to come soon.