

Just In Time HSP and RCR Information

The Collaborative IRB Training Initiative (CITI) web-based learning management platform provides initial human subject protection (HSP) training and three-year renewal HSP training courses. The initial HSP training provides a comprehensive overview of the regulatory framework and ethical principles involved in the conduct of human research. Learners gain an appreciation of historical events that influence the development of current regulatory requirements. Modules outlining the role of the Institutional Review Board (IRB) and the various IRB review mechanisms prepare new investigators to navigate the review and approval process. Additional modules cover the core fundamental tenets of research protections including informed consent, privacy and confidentiality, conflict of interest management, and data safety monitoring and reporting. Separate modules on specific classes of vulnerable subjects prepare the learner to consider and implement safeguards and protections where applicable (i.e., children, prisoners, pregnant women, fetuses, neonates, students, vulnerable international, cultural or community groups). Learners are able to recognize risks and benefits unique to social and behavioral research (SBR) as well as ethical considerations for common SBR research techniques such as records review or internet research. Modules specific to biomedical research cover the regulatory requirements for research regulated by the Food and Drug Administration (FDA) as well as ethical and regulatory issues involved with the conduct of genetic research. Examples and cases throughout the course help the learner apply the core ethical principles of beneficence, respect for persons and justice to their human research. The CITI HSP renewal courses provide a comprehensive review of core material provided in the initial HSP training. Topical information and regulatory updates are incorporated throughout the renewal training modules. The course serves to remind investigators of the fundamental ethical principles while informing them of regulatory changes and relevant trends in human research protections.

Along with HSP training, the University of Kentucky requires both in-person and online Responsible Conduct of Research (RCR) training every other year guided at ethical issues related to mentoring, conflict of interest, data management, reproducibility, peer review, and research misconduct. The College of Health Sciences Office of Research and Scholarship (ORS) helps researchers to maintain compliance in these areas.