

15.0 Education and Training in Human Research Protections

- I. Responsibility for the education and training program
 - A. The HRPP Director, under the leadership of the Associate Vice Chancellor for Compliance, is responsible for evaluating the adequacy of education and training resources for research personnel, HSC members and HSC staff.
 - B. Education efforts are coordinated by the Compliance Education Manager.
 - C. Education and training is maintained through in-person presentations, online tutorials, web resources such as Fact Sheets and Frequently Answered Questions, and email reminders to research personnel.
 - D. Annually, the HRPP Director evaluates current training to update materials based on new developments in regulations and common compliance problems that have arisen during HSC review.
 - E. If a critical issue arises, or if a serious compliance violation indicates the need for prompt dissemination of information, the research community may be notified by email, website, special presentations or communications sent through Department Chairs and Center Directors.

- II. Research personnel training
 - A. All KUMC research personnel, KUMC staff and affiliated staff who have any role in research involving human subjects must complete a seven-module tutorial on human subjects protection and privacy regulations. This population includes principal investigators, co-investigators, sub-investigators, study coordinators, research assistants, and anyone directly and knowingly assisting with the study (i.e., support staff, secretaries and assistants who help complete research related paperwork, etc). Completion of the seven-module tutorial is a one-time requirement.
 - B. KUMC study personnel have a requirement for an annual refresher on human subjects protection. Training may be updated through completion of the KUMC online refresher module or attendance at an in-person refresher presentation.
 - C. The requirement to maintain current training also applies to collaborators from other institutions who are working on KUMC projects. Collaborators who have not had any human subjects training in the past two years may use the KUMC tutorial to maintain their current status at KUMC. Alternatively, they may demonstrate recent human subjects training from their home institution or from NIH.
 - D. When new protocols are submitted to the HSC, HSC staff confirms training in human subjects for all listed study personnel. Final HSC approval is withheld until training for all study personnel is verified.
 - E. The HRPP provides additional opportunities for ongoing education through periodic compliance presentations and announcements about updates to the HRPP website.
 - F. HSC recognizes that maintenance of professional credentialing and training is an important component of ensuring subject safety. Each new submission contains

an attestation by the department chair that the principal investigator is qualified to conduct the study. The HSC requires research team members described in each protocol to be qualified to perform the research procedures that they have agreed to perform; however, the PI is responsible for assembling a team that has the proper qualifications. The KUMC Medical Staff Office has policies that govern what procedures individuals are credentialed to perform. The HSC works closely with the credentialing offices to assure that these policies are followed in the conduct of research and expect credentialing offices to report any problems with credentialing to the HSC.

III. HSC member training

- A. New members undergo an orientation process. After an initial meeting with the IRB Administrator, they are supplied with the OHRP IRB Guidebook, the FDA Information Sheets, and HSC review tools. New members observe at least two committee meetings before they are given studies to review.
- B. For ongoing training, members are provided with copies of the newsletter “IRB: Ethics and Human Research.” Additionally, HRPP staff members provide ongoing training at the meetings by presenting a brief discussion of current topics in human research protection or KUMC research policy.
- C. Periodically, the HRPP surveys the HSC members about their needs for continuing education and the best methods of meeting those needs.

IV. HSC staff training

- A. The HSC Chair, HRPP Director and IRB Administrator attend annual professional conferences. HSC staff are offered periodic opportunities to attend training conferences.
- B. HSC staff maintain their training through discussions at regular staff meetings and attendance at internal compliance presentations.

References:

45 CFR 46.107

21 CFR 56.107