Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
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Section: IRB Education and Training
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Subject: Investigator and Key Study Personnel Training

Policy:
It is the policy of the Human Research Protections Program (HRPP) that all Investigators and key study personnel conducting human subjects research under the jurisdiction of the VUMC IRB complete initial and annual human research protections training.

I. Initial Training. Basic initial training is obtained through the following options:
   A. The Learning Exchange. Search for the module “Human Subjects Protections: Basic Course.”
   B. The CITI Program. Choose either the Basic “Biomedical” or “Social and Behavioral” Research Course.
   C. A Good Clinical Practice course.

II. Annual Training. There are several annual training options for the Principal Investigator and key study personnel. Any one of the following options will count:
   A. Any online VHRPP sessions through The Learning Exchange;
   B. An in-person training session (e.g., News You Can Use, IRB Essentials, or departmental in-services);
   C. An optional course through the CITI Program (e.g., Good Clinical Practices or Responsible Conduct of Research) or any module relative to human subjects protections;
   D. Completion of the OHRO “Investigator 101” training module;
   E. Attendance of a local or national conference regarding human subjects protections; or
   F. Other training may be approved on a case-by-case basis if the content includes human subjects protections. Approval by an HRPP RCA, Manager is required.
   G. With the exception of adverse events and reports of noncompliance, the Investigator and key study personnel are unable to submit through the online submission system until they have completed human subjects training and are not approved to conduct the research.

III. The Investigator’s Handbook is a resource manual for researchers in Behavioral/Social and Health Sciences. These manuals will assist the Investigators in smoothly navigating the IRB process and adhering to the federal regulations and IRB policies related to human research protections. The manuals are located on the HRPP website.

IV. All Investigators and key study personnel conducting research involving humans are encouraged to review the core training materials including the HRPP policies and procedures, The Belmont Report, the federal regulations including 45 CFR 46, 21 CFR 50 and 56, links to federal agencies governing human subjects research, and links to other various agencies and resources (e.g., National Institutes of Health, Food and Drug Administration, Office of Human Research Protections, National Bioethics Committee, etc.). These links are available on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
V. The HRPP will send mass e-mail notifications, limited to a mailing list of all Investigators and key study personnel that have active studies, to alert them of pertinent IRB issues or decisions that may impact their research.

VI. All new Investigators, key study personnel, and graduate students are encouraged to attend an IRB Research Matters workshop in preparation for the ethical conduct of human subjects research and an overview of the federal regulations governing HRPP and IRB operations and research involving human participants.

VII. The HRPP Reference Library houses information on assorted topics regarding the history and conduct of research activities. These resources will be available for checkout upon request.

References:
Collaborative IRB Training Initiative (CITI): http://www.citiprogram.org
HRPP VIII.A.1 - Procedure for Investigator and Key Study Personnel Training