Vanderbilt University  
Research Education and Training Requirements

Procedure:
This procedure defines the process of meeting the educational requirements for Investigators and key study personnel (KSP) conducting research involving humans under the jurisdiction of the Human Research Protections Program (HRPP), Vanderbilt University (VU), and Vanderbilt University Medical Center (VUMC).

I. IRB Requirements: All investigators and KSP must complete an initial basic course in good clinical practice (GCP) and human subjects protections prior to engaging in any research activities that include interacting with potential participants or their information. GCP and human subjects training is expected to be renewed every three (3) years for VU and VUMC users.

A. Initial Training for VU Users:
Basic initial training is obtained through the following options:

1. A Good Clinical Practice course. GCP training is required for anyone who is involved in the conduct, oversight, or management of clinical trials and must be completed prior to beginning research-related activities.
   a) GCP Courses for Bio-Medical Investigators and KSP
      (1) The CITI Program. Choose either the Basic “GCP for Clinical Investigations of Drugs and Biologics (ICH)” or “GCP for Clinical Investigations of Drugs and Biologics (FDA)” or “GCP for Clinical Investigations of Devices.”
      (2) NIAID offers a self-paced 14 module course.
      (3) NIDA offers a self-paced 12 module course.
   b) Once you finish the training, please document it by completing this REDCap Survey. Many of you may have already completed GCP training. If you completed it in the last three (3) years, please document it by completing this REDCap Survey.

2. If GCP training is completed, the following human subjects training for the purpose of IRB applications is not needed:
   a) Oracle Learning. Search for “HRPP Basic Module”.
   b) The CITI Program. Choose either the Basic “Group 1: Biomedical” OR “Group 2: Social and Behavioral” Human Research Course.
B. Initial Training for VUMC Users:
Basic initial training is obtained through the following options:

1. A Good Clinical Practice course. GCP training is required for anyone who is involved in the conduct, oversight, or management of clinical trials and must be completed prior to beginning research-related activities.
   a) **GCP Courses for Bio-Medical Investigators and KSP**
      (1) The CITI Program. Choose either the Basic “GCP for Clinical Investigations of Drugs and Biologics (ICH)” or “GCP for Clinical Investigations of Drugs and Biologics (FDA)” or “GCP for Clinical Investigations of Devices.”
      (2) NIAID offers a self-paced 14 module course.
      (3) NIDA offers a self-paced 12 module course.

   **GCP Training for Social and Behavioral Investigators and KSP**

   b) Once you finish the training, please document it by completing this REDCap Survey. Many of you may have already completed GCP training. If you completed it in the last three (3) years, please document it by completing this REDCap Survey.

2. If GCP training is completed, the following human subjects training for the purpose of IRB applications is not needed:
   a) The Learning Exchange. Search for the module “HRPP Basic Module”.
   b) The CITI Program. Choose either the Basic “Group 1: Biomedical” OR “Group 2: Social and Behavioral” Human Research Course.

C. Other Requirements (if applicable):

1. Protection of Minors: To meet the Vanderbilt University policy compliance requirement for training, prior to interaction with minors in Vanderbilt programs and operations, all staff, faculty, students, and others with a VUNet ID access must complete training. Training must be renewed on an annual basis is continued interaction with minors will occur.
   a) **VU Users:** Oracle Learning. Search for “Protection of Minors 101” or “Protection of Minors Annual Renewal (for renewals only).”
   **VUMC Users:** The Learning Exchange. Search for the module “POM Training for Employees Working in Programs with Minors.”

   b) VU students will complete training via Your Enrollment Services (YES). Select the Online Module Program link. Search for “Protecting Youth” or “Protection of Minors Annual Renewal (for renewals only).”

2. Responsible Conduct of Research (RCR): The NIH requires training for graduate students and postdoctoral researchers with a NRSA fellowship. The National Science Foundation (NSF) requires training for all participants sponsored by NSF awards. RCR training must be renewed every five (5) years.
   a) The CITI Program. Choose “Responsible Conduct of Research (RCR) Basic.”