Procedure

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

Procedure:
This procedure defines the process of meeting the educational requirements for Investigators and key study personnel conducting research involving humans under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator and Key Study Personnel Responsibilities
A. Initial Training. All Investigators and Key Study Personnel must complete an initial basic course in human subjects protections prior to engaging in any research activities that include interacting with potential participants or their information. Options for initial training are:
   1. The Learning Exchange module titled “Human Subjects Protections: Basic Course”;
   2. The CITI Program’s Basic Biomedical or Social and Behavioral Course; or
   3. A Good Clinical Practice Course. GCP training is required for anyone who is involved in the conduct, oversight, or management of clinical trials. This training will count as human subjects training.
      a) Investigators and key study personnel must complete GCP training prior to beginning research-related activities. GCP training that has been completed within the past 3 years will be accepted. To document GCP training, complete the GCP Training REDCap Survey at https://redcap.vanderbilt.edu/surveys/?s=JFPH8K33HE
      b) Users will be asked to upload a copy of the training certificate in REDCap showing which course they completed and the completion date. The date will be the trigger for a 3-year reminder.
B. Annual Training. There are several annual training options:
   1. Any online VHRPP training modules through The Learning Exchange;
   2. An optional course through the CITI program (e.g., Good Clinical Practices or Responsible Conduct of Research); or
   3. Attendance of at least one HRPP educational course (e.g., IRB Essentials, IRB News You Can Use, and/or IRB Research Matters); or
   4. Completion of the OHRP "Investigator 101" training module; or
   5. Attendance of a local, regional, or national conference regarding human research protections
C. Every three years, GCP training must be completed again for anyone who is involved in the conduct, oversight, or management of clinical trials. There are several ways to complete GCP training:
   1. CITI offers a GCP Course as well as refresher courses;
2. NIAID offers a self-paced 14 module course;
3. NIDA offers a self-paced 12 module course;
4. Best Practices in Good Clinical Trials offers courses for VU or VUMC through the Learning Exchange; or

D. The Investigator will utilize the appropriate Investigator’s Handbook to assist in navigating the IRB process and adhere to the federal regulations and HRPP policies related to human research protections. The manuals are located on the HRPP website http://www.mc.vanderbilt.edu/irb/education/.

E. The Investigator and key study personnel will keep abreast of current events and review the HRPP website for current HRPP policies and procedures and the federal regulations, especially those applicable to their area of research. The website includes the following:
   1. VU and VUMC's Federalwide Assurances;
   2. The IRB Committee Rosters;
   3. An HRPP Contact List;
   4. HRPP Sites of Interest;
   5. An HRPP Training Plan;
   6. IRB and Radiation submission portal;
   7. The IRB Workshop Schedule;
   8. The Investigator's Manual;
   9. The NIH Online Course;
   10. The HRPP Organizational Chart;
   11. HRPP Policies and Procedures;
   12. HRPP and IRB Roles and Responsibilities;
   13. Template Language for Informed Consent Documents; and
   14. Links to various Agencies and Resources such as:
       a) National Institutes of Health;
       b) Food and Drug Administration;
       c) Office for Human Research Protections; and
       d) National Bioethics Committee.

F. Investigators and key study personnel are encouraged to attend additional educational opportunities sponsored by the HRPP throughout the year.
   1. Research Matters Courses are available on the Learning Exchange. The course consists of discussion of the history of human research; a description of the ethical principles underlying the conduct of human subjects research and an overview of the federal regulations governing HRPP operations and research involving human participants.
   2. IRB Essentials sessions are conducted frequently to provide education about HRPP policies and procedures, forms and processes.
   3. IRB News You Can Use sessions are conducted to provide education on "hot topics" and important issues.
   4. The IRB Committees may request individualized education to research Investigators and/or their staff in response to deficiencies identified by the Committee.

G. Other resources available to Investigators and key study personnel
   1. HRPP Brochures:
       a) "Are You Conducting Human Subjects Research?" This brochure targets Investigators and Key Study Personnel to provide basic information about the IRB process including
          (1) The role of the IRB;
(2) Definition of research and human subject;
(3) Requirements for conducting research involving humans;
(4) Types of IRB review;
(5) Requirements when performing research at other sites;
(6) Definition of informed consent and elements;
(7) Resources for additional information; and

2. “HIPAA and Research.” This brochure is a quick reference guide for Investigators and Key Study Personnel, and includes the following information:
   a) A description of HIPAA;
   b) A list of direct identifiers;
   c) HIPAA rules in regards to research involving humans;
   d) Tracking of disclosures; and
   e) Website addresses for additional information.

3. Project PROTECT. The goal of project PROTECT is to develop an electronic system that assists Investigators precisely at the time of proposal development of human research by teaching the important protections mandated in accordance to regulatory mandate and ethical guidance. The hypothesis is that by providing Investigators will well-integrated, electronically-linked/trigger decision support tools to use at the time of IRB proposal development will improve the quality of IRB applications and the protection of human participants. These improvements will decrease the time and complexity of IRB review allowing Investigators and reviewers to focus on more complex issues that, by necessity, fall outside the standardized decision support system. In addition the hypothesis that if appropriately designed, the tools developed will gain widespread acceptance if they are intuitive, functional and delivered through a common user interface on a readily available platform.

4. Project IMPACTT. IMPACTT (IRB Measured Performance and Collaborative Training Techniques) is a quality improvement program designed to assist Investigators in research involving humans. The goals of this initiative are three fold: to assist the research team in identifying strengths and weaknesses, to provide education, and to make recommendations for improvement in their research program. To accomplish these goals, the HRPP invites Investigators or randomly selects an Investigator to participate in this initiative. The IMPACTT Consultation Team will perform a short-preliminary interview to explain these goals. The IMPACTT team will then conduct on-site assessments examining the necessary elements involved in managing a research study. At the conclusion of the on-site assessment, an exit interview will be scheduled to discuss the assessment with the Investigator and Key Study Personnel. A final report will then be generated which includes the findings and recommendations to improve the overall research program of the Investigator and his or her Key Study Personnel.

H. The Investigator will keep all IRB applications current with Investigator and key study personnel contact information to facilitate the receipt of all mass e-mail notifications alerting them of pertinent IRB issues or decisions that may impact their research.

II. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will verify in the HRPP database the completion of the Investigator and key study personnel training requirements as stated above.
B. The RCA will notify the Investigator and key study personnel that the IRB training requirements must be met prior to the initiation of research involving humans under the jurisdiction of the IRB.

C. The HRPP staff are available Monday through Friday 8:00 a.m. – 5:00 p.m. at 322-2918 to answer questions and assist Investigators or key study personnel with any educational needs.

References
HRPP VIII.A - Investigator and Key Study Personnel Training