Procedure

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. Effective October 1, 2003, all Investigators and key study personnel, who have not previously completed the Vanderbilt Human Research Protection Training, must complete the CITI Basic Course in either Biomedical Research or Social Behavioral Research.

1. Required CITI modules;
2. Instructions for Completing CITI Training.

a) The CITI program may be accessed through the HRPP website at http://www.mc.vanderbilt.edu/irb/. The Investigator and key study personnel can access a link to the CITI program. Alternatively, the CITI program may be accessed directly at http://www.citiprogram.org.

b) The Investigator and key study personnel can log onto the CITI website and complete the set of modules most applicable to the type of research to be conducted and take all applicable quizzes for each module, with a minimum score of 80% in order to pass.

(1) Biomedical Research Modules:
   (a) Module 1 - History and Ethical Principles;
   (b) Module 2 - Basic IRB Regulations & Review Process; and
   (c) Module 3 - Informed Consent.

(2) Social/Behavioral Modules:
   (a) Module 1 - History and Ethical Principles - SBR;
   (b) Module 2 - The Regulations and the Social And Behavioral Sciences - SBR;
   (c) Module 3 - Informed Consent - SBR; and
   (d) Module 4 - Privacy and Confidentiality - SBR.

3. A minimum score of 80% must be obtained. Investigators and key study personnel not reaching a passing score will need to review the content of the modules and re-take the exam until a score of ≥80% is obtained. If the Investigator or key study personnel is experiencing difficulty with a particular component of the exam, they may contact the HRPP at 322-2918 and request to speak with a representative of the HRPP Process Improvement team.

B. Annual Training. Effective October 1, 2004, all Investigators and key study personnel must complete annual continuing education related to ethical and regulatory aspects of research involving humans. Appropriate documentation will need to be provided to the HRPP demonstrating compliance with annual training requirements. This training requirement may be satisfied with the completion of one of the following:

1. A refresher course through the CITI program; or
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. 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/.

D. 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;
14. The Training Compliance Statement; and
15. 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.

E. Investigators and key study personnel are encouraged to attend additional educational opportunities sponsored by the HRPP throughout the year.
1. Research Matters Courses are conducted quarterly. 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 monthly to provide education about HRPP policies and procedures forms and processes.
3. IRB News You Can Use sessions are conducted at least every other month, alternating between Behavioral/Social Science and Health Science issues, to provide education on "hot topics" and important issues.
4. The HRPP Process Improvement Team, as directed by the IRB Committees, provide individualized education to research Investigators and/or their staff in response to deficiencies identified by the Committee. In addition, the HRPP Process Improvement Team will provide any type of human research protections training at the department's or Investigator's request.

F. 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 human;  
      (4) Types of IRB review;
      (5) Requirements when performing research at other sites;  
      (6) Definition of informed consent and elements;
II. HRP Administration Responsibilities.

A. The HRPP will maintain the collaborative agreement with the University of Miami CITI program or equivalent training for Investigator and key study personnel training. The HRPP will maintain a record system of the completion of such modules.

B. The HRPP will assist each Investigator or key study personnel having difficulty successfully completing the required module quizzes with a score of ≥80%.

C. The HRPP will conduct educational sessions throughout the year for all faculty and staff.

D. The HRPP will maintain its website with links to federal, state and institutional resources.

E. The HRPP maintains a contact database for research personnel. This database contains the individual's human subject training status. The system automatically notifies PIs and key study personnel approximately 4 weeks in advance of their need to provide the HRPP with verification of their continued HSP training.

G. 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.

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.

(7) Resources for additional information; and
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.