Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: VIII.C.1
Section: IRB Education and Training
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Subject: Procedure for HRPP Staff Training

Procedure:
This procedure outlines the process for completing the human research protections educational requirements for the Human Research Protection Program (HRPP) staff member.

I. HRPP Staff Member Responsibilities.
   A. New hires to VUMC complete a general orientation program conducted by The Learning Center including Making a Difference and Hearts and Minds orientations. The VUMC orientation is an introduction to the working environment at the Medical Center and includes: the mission, the vision, the credo, the expectations about service, performance and relationships, and it achieves initial safety regulatory requirements.
   B. New HRPP staff members complete the Collaborative IRB Training Initiative (CITI) training modules. This internet-based course in human research protections and bioethics is designed specifically for all personnel that have a significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. The course consists of training modules that are divided into two tracks: Biomedical Research and Social/Behavioral Research. The new RCA completes all of the modules in the track that is the focus of the team in which they are a member. The HRPP Staff member logs onto http://www.citiprogram.org and complete set of modules most applicable to the type of research to be reviewed.
      1. Biomedical Research Modules:
         a) Module 1- History and Ethics;
         b) Module 2- Defining Research and Regulatory Overview; and
         c) Module 3- Informed Consent.
      2. Social/Behavioral Modules:
         a) Module 1- History and Ethics;
         b) Module 2 – Defining Research;
         c) Module 3- Regulatory Overview; and
         d) Module 5- Informed Consent.
      3. A minimum score of 80% must be obtained. HRPP Staff members 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.
   C. The new HRPP staff member completes the three Office for Human Research Protection’s (OHRP) Training Modules for Assurances. This tutorial explains the responsibilities involved in an institutional program of human research protections, as well as the informed consent process from the perspective of OHRP and is required to be completed within the initial 3 months of employment in the HRPP.
   D. The new HRPP staff member attends and observes at least one health science (HS) and behavioral science (BS) committee meeting for each of the four IRB Committees and observe the post-Committee
work with the Regulatory Compliance Analyst (RCA) team.

E. The new HRPP staff member attends a Research Matters Course. This course consists of discussion of human participant research; a description of the ethical principles underlying the conduct of human research; and an overview of the federal regulations governing IRB operations and human research.

F. New HRPP Staff members spend up to one week under the mentorship of an RCA who provides an overview of the following:
   1. The Belmont Report;
   2. Federal Regulations:
      a) DHHS 45 CFR 46; and
      b) FDA 21 CFR 50 and 21 CFR 56.
   3. Committee Review Process;
   4. Expedited Review Process;
   5. Exempt Review Process;
   6. HRPP Policies and Procedures;
   7. Job Description and Key Functions; and

G. New HRPP Staff members receive an overview of reference websites which includes the following:
   1. HRPP Contact Information;
   2. §45 CFR 46 & Expedited Categories;
   3. §21 CFR 50 & §21 CFR 56 – FDA Regulations;
   4. FDA Fact Sheets;
   5. §21 CFR 361 – RDRC Regulations;
   6. OHRP Flow Charts;
   7. OPRR (OHRP) Common Findings & Guidance (11/98);
   8. Ethical Guidelines:
      a) Nuremberg Code;
      b) Declaration of Helsinki; and
      c) The Belmont Report;
   9. VU and VUMC’s FWAs;
   10. FERPA;
   11. Vulnerable Populations;
      a) Chapter 6 – IRB Member Guidebook – Special Classes of Subjects
      b) Vulnerable Population Checklists & Points to Consider;
   12. HRPP Publications;
   13. VU Memorandums of Understanding (MOU);
   14. Various OHRP Guidance Documents:
      a) Certificates of Confidentiality; and
      b) Continuing Review;
   15. Exemption for Demonstration Projects on Public Benefit or Service Programs
   16. Informed Consent Requirements in Emergency Research;
   17. Exculpatory Language in Informed Consent;
   18. Prisoner Research;
   19. Research Use of Stored Data or Tissues;
   20. Health Law Handbook (excerpts); and

H. The HRPP Reference Library houses information on assorted topics related to issues and regulations on human research protections. The materials are available for checkout upon request.

I. All HRPP staff members are expected to attend the following during each year (12 months) of employment:
   1. A minimum of one local, regional or national conference in human research protections
   2. A minimum of four educational sessions; however, staff are
encouraged to attend 12 informal, locally available educational sessions during a 12-month period. This includes but is not limited to:

a) IRB Essentials Sessions;
b) IRB News You Can Use Sessions;
c) Clinical Research Staff Council Forum;
d) Ethics Conferences;
e) GCRC monthly meetings;
f) Continuous Quality Improvement Conferences; and
g) Other research or human protections related education offerings sponsored by internal departments or external offerings such as those sponsored by Meharry, Fisk, MTSU, etc.

3. Attendance at the mandatory annual training.
5. Annually complete the VUMC requirements (e.g., Fire Safety, Universal Precautions, etc.).

J. It is the responsibility of the staff member to seek out and identify educational opportunities and develop a budget for the proposed educational opportunity. These educational sessions must be submitted to the RCA Team Leader for incorporation into the HRPP professional development plan and budget. The HRPP Director gives final approval for attendance to requested professional development opportunities.

K. Staff members are required to obtain IRB certification. Staff members are placed on a rotating schedule depending on experience, length of time in department, and certification eligibility requirements. Initial certification and recertification costs are paid for by the HRPP. Staff members are encouraged to use the HRPP library for study materials to prepare for the exams.

1. The applicable job description for the RCA designates a specific time frame for the completion of the Certified IRB Professional (CIP) exam. The Council for Certification of IRB Professionals (CCIP) is a program that has established certification standards and mechanisms with the input from a group of experts representing a broad diversity of practice and experience in the field of human research protections. The certification examination evaluates an individual's knowledge of ethical principles, historical events, regulatory requirements, and operational and functional issues relating to IRBs and human research protections programs.

2. Other highly desirable certifications include:
   a) Association of Clinical Research Professionals (ACRP): Certified Clinical Research Coordinator (CCRC) or Certified Clinical Research Associate (CCRA);
   b) Society of Clinical Research Administrators (SoCRA): Certified Clinical Research Professional (CCR); and
   c) Regulatory Affairs Professionals Society (RAPS): Regulatory Affairs Certified (RAC).

II. HRPP Regulatory Compliance Analyst (RCA) Team Leader Responsibilities.
A. The RCA Team Leader assures completion of the new staff member checklist.
B. The RCA Team Leader evaluates the progress of each new Staff member at three and six-months from his or her hire date. A copy of the written evaluation is provided to the new staff member, the Team Leader, and the HRPP Director.

1. This evaluation includes:
a) A test composed of ten questions to evaluate the new Staff member’s basic knowledge of ethical principles and federal regulations;

b) An audit of research studies processed by the new Staff member to include quality assurance review of the data entry in the HRPP database system as compared to the research study file and

c) Agendas and minutes composed by the new Staff member will be reviewed and evaluated.

2. A plan of action is developed at the three-month evaluation period in the areas identified as needing additional education, training, and development.

3. It is expected that the new staff member would be satisfactorily performing all key functions of the job at the six-month evaluation point.

C. The RCA Team Leaders conduct annual performance evaluations for all staff members that report to them.

D. The RCA Team Leaders provide ongoing coaching and mentoring of their team members with appropriate performance improvement counseling in accordance with institutional policy as necessary.

References

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