



VANDERBILT®

Human Research Protections Program Education Plan

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Human Research Protections Program
≈ 3319 West End Ave., Suite 600, Crystal Terrace, Nashville, Tennessee 37203 ≈
phone 615-322-2918 ≈ fax 615-343-2648
website <http://www.mc.vanderbilt.edu/irb/>

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INTRODUCTION

The Human Research Protection Program (HRPP) is committed to providing high quality, comprehensive education and training for HRPP staff, IRB Committee members, and Investigators and their staff regarding human research protections, current events, federal regulations and HRPP policies and procedures.

I. HRPP STAFF

A. Staff Orientation

An individualized education checklist will be initiated by the Team Leader for all new staff and completed within three months of the staff member's hire date.

Vanderbilt University Medical Center (VUMC) requires all newly hired VUMC employees attend a general orientation program conducted by The VUMC Learning Center. This orientation is an introduction to the working environment at VUMC and includes: Vanderbilt's history and mission, the vision, the credo; the expectations about service, performance and relationships; and it completes the mandatory safety regulatory requirements which include hazard communication, fire safety and emergency preparedness, ergonomics, and personal safety.

All new HRPP Regulatory Compliance Analyst (RCA) will complete the following training during orientation:

HRPP Human Subjects Training; Basic Course, in LMS. 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 Basic Course consists of the basic elements of Biomedical Research and Social/Behavioral Research. There are other modules which pertain to Human Subjects Protection in the LMS system that focus on particular elements of the conduct of research at Vanderbilt. The new RCA may also be assigned additional modules that are more specific to Behavioral or Biomedical research, depending on which team they are assigned.

1. 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, as well as the informed consent process from the perspective of the OHRP and is required to be completed within the initial 3 months of employment in the IRB.
2. Committee Meeting Observations. While rotating through each team, the RCA will observe each team and respective Committee meetings while learning committee work (round table, letters to Investigators, minutes) with the team.
3. HRPP Research Matters Course. The RCA will attend 1 course. This course consists of discussion of human research; a description of the ethical principles underlying the conduct of research involving humans; and an overview of the federal regulations governing HRPP operations and research involving humans.

4. Initial Orientation. New HRPP staff members will begin orientation under the direction of the Team Leader in conjunction with an assigned preceptor who will provide an overview of the following:

- Ethical Obligations Including *The Belmont Report*;
- Federal Regulations - DHHS 45 CFR 46, FDA 21 CFR 50 and 56;
- HRPP Policies and Procedures;
- Levels of IRB Review Including Standard, Expedited, Exempt, Non-Human/Non-Research;
- Vulnerable Populations;
- Conflicts of Interest;
- Verification of IRB Approval and FWA at External
- Sites Engaged in Research;
- Definition of Industry-Initiated Studies Including IRB Fees;
- IRB Communication Process;
- Agenda and Minutes;
- Committee Action and Approval Letters;
- Update of the HRPP Database;
- Continuous Quality Improvement and Quality Assurance;
- Job Description and Key Functions; and
- Evaluation Process Including Scoring Criteria.

5. New HRPP staff members are trained on where to obtain information from resources which include the following:

- HRPP Contact Information;
- 45 CFR 46 & Expedited Categories;
- 21 CFR 50 and 56 – FDA Regulations;
- FDA Fact Sheets;
- 21 CFR 361 – RDRC Regulations;
- OHRP Human Subject Regulations Decision Charts;
- Ethical Guidelines:
 - *Nuremberg Code*
 - *Declaration of Helsinki*
 - *The Belmont Report*;
- Federal Wide Assurances;
- FERPA;
- Vulnerable Populations;
- Chapter 6 – IRB Member Guidebook – Special Classes of Subjects;
- Vulnerable Population Checklists & Points to Consider;
- HRPP Publications;
- VU and VUMC Memorandums;
- Various OHRP Guidance Documents;
- Certificates of Confidentiality;
- Continuing Review;
- Exemption for Demonstration Projects on Public Benefit or Service Programs;
- Informed Consent Requirements in Emergency Research;
- Exculpatory Language in Informed Consent;
- Research Use of Stored Data or Tissues;
- Health Law Handbook (excerpts); and
- HRPP Policies & Procedures.

6. The assigned preceptor and/or the RCA Team Leader will evaluate the progress of each new staff member at three and six months from his or her hire date. The evaluation will consist of an assessment of the key functions of the position. Input will be obtained from the IRB Chairperson, and/or other staff members as applicable. A copy of the written evaluation is provided to the new staff member, Team Leader, and the HRPP Director(s). This evaluation includes:
 - a. 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; and
 - b. A review and evaluation of agendas and minutes composed by the new staff member.
 - c. A plan of action is developed at the three-month evaluation period in the areas identified as needing additional education, training, and/or development.
 - d. It is expected that the new staff member would be performing adequately in all key functions of the job at the six-month evaluation point.
7. The assigned preceptor and/or Team Leader will complete a formal six-month evaluation as required by VUMC Human Resources. The new staff member's progress will be discussed and an action plan for any areas of deficiency will be developed. The Team Leader will also develop departmental and personal goals in conjunction with the staff member for the remainder of the orientation period.

B. HRPP Staff Continuing Education

1. All HRPP staff members are expected to attend the following during each year (12 months) of employment:
 - a. One national convention or regional conference in human research protections;
 - b. 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:
 - i. HRPP Essentials Sessions;
 - ii. HRPP News You Can Use Sessions;
 - iii. HRPP Brown Bag Sessions
 - iv. Clinical Research Staff Council Forum;
 - v. Ethics Conferences;
 - vi. CRC Weekly Meetings;
 - vii. Local SoCRA Chapter Meetings;
 - viii. Local ACRP Chapter Meetings;
 - ix. Continuous Quality Improvement Conferences; and
 - x. Other research or human protections related education offerings sponsored by departments of VU or VUMC, or external offerings such as those sponsored by Meharry, Fisk, MTSU, etc.
 - c. Annual IRB Training; and
 - d. All scheduled staff meetings.

2. In addition, all HRPP staff members are expected to sign and/or complete the following on an annual basis:
 - a. HRPP Confidentiality Agreement;
 - b. HRPP Database Use Confidentiality Agreement;
 - c. Conflict of Interest Declaration;
 - d. Flexible Work Schedule Agreement, if applicable; and
 - e. Annual VUMC requirements which include:
 - i. Standards of Conduct/ "Do the Right Thing";
 - ii. VUMC Policy Review;
 - iii. VUMC Universal Safety Training;
 - iv. VUMC Confidentiality Agreement;
 - v. HIPAA; and
 - vi. Conflicts of Interest.

3. Staff members are required to obtain CIP certification. Staff members are placed on a rotating schedule depending on experience, length of time in department, and certification eligibility requirements. The HRPP utilizes the following certifications:
 - a. Certified IRB Manager (CIM): After one year of experience with the HRPP, the staff member will be eligible for the Certified IRB Manager Examination. This certification is designed for individuals who are responsible for oversight of Human Research Protection Programs. The exam contains 150 questions in a multiple choice and true or false format. Content includes: Regulatory Requirements, Informed Consent Requirements, Research History, Medical Ethics, IRB Administration, Guidance Documents, FDA and DHHS Regulatory Differences, HIPAA Requirements, and IRB Management.

 - b. Certified IRB Professional (CIP). 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.

4. Additional Educational Opportunities
 - a. Personality assessments will be voluntarily administered to employees to help improve work and personal relationships, increase productivity, and identify leadership and interpersonal communication preferences. The goal is to help people understand themselves and each other so that they might work more effectively with others.

 - b. Team building workshops will be offered to HRPP staff members throughout the year as an opportunity to better understand the dynamics of effective teams, encourage embracement of new concepts, strategies to minimize conflict and maximize performance in a team setting including understanding team roles and team effectiveness.

 - c. Facilitative Leadership Training will be offered as a continuing education opportunity to all HRPP staff members. The goal of facilitative leadership training is to develop behaviors that enhance the collective ability of employees to adapt, solve problems, and improve performance. Facilitative skills should be utilized to effectively lead and actively participate in the HRPP Team and Committee meetings.

- d. Continuous Quality Improvement training is encouraged as all staff members are responsible for CQI activities in their individual and team-work processes. The goal of this training is for all staff members to understand the CQI process of “plan, study, do, and act.” This provides a framework for identifying areas for improvement, the development of action plans and follow-up to evaluate the effectiveness or resolution of identified concerns.
 - e. The HRPP reference library is available for all staff members to obtain additional information regarding the history and conduct of research activities, HIPAA regulations, IRB brochures, CDs and binders of recent conference materials, writing guidelines, and regulatory documents. The library also includes CDs and videotapes focusing on the elements of informed consent, instructional modules for protecting human research participants, IRB review criteria, basic ethical principles and their application.
5. All staff members will complete a self-evaluation annually. The Team Leader will conduct an annual performance evaluation based on the employee’s input and focused on identifying strengths and developing an action plan for any areas of weakness. This is a collaborative process to facilitate the employee’s personal and professional growth. Clear and specific goals will be developed together to help achieve the employee’s potential and the department’s objectives.

II. VU IRB COMMITTEE MEMBERS

A. Initial Orientation

1. All new Committee members are required to complete an initial orientation before being allowed to serve on the IRB Committee, which includes the following:

A two-hour educational session with a HRPP Manager, or designee, detailing:

- HRPP Policies and Procedures;
- DHHS Regulations 45 CFR 46;
- FDA Regulations 21 CFR PART 50 and 56;
- Applicable State and Federal Laws;
- Committee Member Responsibilities;
- Types of Review Including Exempt, Expedited, Full Committee, Umbrella, Repository;
- Primary and Secondary Reviewer Assignments and Responsibilities;
- Distribution of Materials for Review;
- Pre-review by Regulatory Compliance Analyst;
- Encourage Contact of Investigators for Additional Information/Clarification to Facilitate Positive Outcome;
- Assessment of Risks;
- Informed Consent Process, Documentation, Required Elements, and Waiver;
- Confidentiality and HIPAA;
- Vulnerable Populations and Supplemental Reviewer's Comment Forms;
- Data Safety Monitoring Plan or Committee;
- Identification of External Sites and Requirements;
- Documentation and Discussion of Review Criteria;
- Motions and Votes;
- Conflicts of Interest;
- Determination of Review Intervals; and
- Attendance, Notification of Absence, and Payment.

Human subjects protections education on the Learning Exchange (LMS). This internet-based collection of training modules involving 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. If the IRB Committee member serves on the Health Science Committee, he or she will complete the Basic module and may be assigned additional modules as appropriate to the Committee they have been assigned.

2. The three OHRP Training Modules for Assurances. This tutorial explains the responsibilities involved in an institutional program of human participant research, as well as the informed consent process from the perspective of the OHRP.

3. Committee Meeting Attendance and Observations. New IRB Committee members must attend and observe at least one IRB Committee meeting prior to functioning as a voting member.
4. Each new IRB Committee member receives the book entitled "Institutional Review Board Member Handbook" by Robert Amdur, and instruction on how to access other resources such as:
 - a. IRB Administrative Information;
 - b. Committee Rosters;
 - c. Federal Regulations;
 - d. HHS Regulations - 45 CFR 46;
 - e. FDA Regulations – 21 CFR PART 50 and 56;
 - f. Significant Differences in the FDA and the HHS Regulations;
 - g. Expedited Categories;
 - h. OHRP Human Subject Regulations Decision Charts (9/98);
 - i. Glossary of Terms;
 - j. Local Guidance Documents and Policies;
 - k. Federal Wide Assurances (FWAs);
 - l. HRPP Website for IRB Policies and Procedures;
 - m. IRB Reviewer's Comment Form;
 - n. Sample IRB Meeting Agenda;
 - o. Agenda Flowcharts;
 - p. Flowchart for PI Reporting of an Adverse Event or Unanticipated Problems Involving Risks to Subjects or Others;
 - q. The Belmont Report; and
 - r. Websites of Interest.

B. IRB Committee Member Continuing Education

1. All IRB Committee members and alternate members are required to attend, listen, or watch a recorded version of IRB Annual training.
2. All IRB Committee members are required to complete a self-evaluation tool assessing their knowledge, and identifying educational needs for the coming year.
3. IRB Committee members are encouraged to participate in at least one additional continuing education opportunity each year. The following are available and participation is encouraged:
 - a. Completion of an HRPP module in the Learning Exchange (LMS);
 - b. Presentations by Investigators;
 - c. Completion of a "refresher" course through the CITI program; or
 - d. Completion of an optional course through the CITI program (e.g., A Good Clinical Practice Course, or a Responsible Conduct of Research course); or
 - e. Attendance of an IRB educational course (e.g., IRB Essentials, IRB News you Can Use, and/or Research Matters); or
 - f. Completion of the OHRP "Investigator 101" training module; or
 - g. Attendance of a local, regional, and national conference regarding human research protections.

4. Monthly education is provided at the IRB Committee meetings.
5. At least one Committee member from each Committee will be encouraged to attend a national or regional human research protections conference annually.
6. The HRPP reference library is available for all IRB Committee members to obtain additional information regarding the history and conduct of research activities.

III. RESEARCH INVESTIGATORS

The June 5th, 2000 NIH Guide Notice mandated all Key Personnel involved in PHS funded human subjects research must have formal instruction in human research protections. This has been embraced by many of the federal agencies; therefore, all human research Investigators and Key Study Personnel must complete the following training:

A. HRPP Human Subjects Protections Education in the Learning Exchange (LMS)

Human subjects protections education on the Learning Exchange (LMS). This internet-based collection of training modules involving 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. If the IRB Committee member serves on the Health Science Committee, he or she will complete the Basic module and may be assigned additional modules as appropriate to the Committee they have been assigned.

1. The learning objectives of the LMS modules are:
 - a. To provide an understanding of the historical perspectives, ethical principles, and Federal regulations associated with the conduct of research with human participants;
 - b. To provide a clear understanding of the basic privacy protections for health information provided by HIPAA and other legal-regulatory sources, and to understand the duties imposed on persons with access to health information in order to secure those privacy protections;
 - c. To provide basic information on the regulations and policies governing research with investigational drugs, biologics, and devices; and
 - d. To provide a clear understanding of the ethical issues and Federal regulations in force during the conduct of Social/Behavioral Research, Records Based Research, and Genetics Research with human participants.
2. All active research personnel are required to participate in at least one additional continuing education opportunity each year. The following are available and participation is encouraged:
 - a. Completion of an HRPP module in the Learning Exchange (LMS);
 - b. Completion of a “refresher” course through the CITI program; or
 - c. Completion of an optional course through the CITI program (e.g., A Good Clinical Practice Course, or a Responsible Conduct of Research course); or
 - d. Attendance of at least one IRB educational course (e.g. IRB Essentials, IRB News You Can Use, and/or Research Matters); or
 - e. Completion of the OHRP “Investigator 101” training module; or
 - f. Attendance of a local, regional, and national conference regarding human research protections.

B. Investigator’s Handbook

The Investigator's Handbook is a resource manual for researchers in Behavioral/Social and Health Sciences. These manuals will assist the Investigators in navigating the IRB process and adhering to the federal regulations and HRPP policies related to human research protections. These manuals will also assist the Investigators in complying with Vanderbilt institutional policies, the HRPP policies and procedures, and the federal regulations concerning the use of human participants in research. The manuals are located on the HRPP website.

C. Additional Educational Opportunities

1. IRB Basics. This course is conducted quarterly and may be provided more frequently by the request of a department, instructor or group of investigators wanting to have the presentation tailored to their group. The course is open to HRPP staff, Committee members, and research Investigators and their staff. The IRB Basics 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. This presentation also includes time for investigators to get assistance with new projects. The Vanderbilt School of Medicine CME Office has approved CME credits for this course.
2. HRPP Essentials sessions are conducted every other month to provide education about HRPP policies and procedures or other topics of interest. The Vanderbilt School of Medicine CME Office has approved CME credits for this course.
3. HRPP News You Can Use sessions are conducted quarterly to provide education in "hot topics" and important issues. The Vanderbilt School of Medicine CME Office has approved CME credits for this course.
4. The HRPP Compliance Team as directed by the IRB Committees provides individualized education to the research Investigators and/or their staff in response to Investigator deficiencies identified by the Committee. In addition, the HRPP staff will provide any type of human research protections training at the department's or Investigator's request. An in-service request form is available on the HRPP website.

D. HRPP Website

HRPP Website consists of the following categories:

1. Contact Us includes the names and contact information for each person within the department, as well as a way for the research community to provide us with feedback, suggestions, and comments. This section also contains the link to request a departmental in-service and the department's organizational chart.
2. About Us provides information regarding the basics of human subjects research, states the current members of each IRB Committee along with past rosters.
3. Policies and Procedures includes the most current HRPP policies and procedures. The procedures are grouped by areas of responsibility in an effort to facilitate the IRB process.
4. Forms includes the most current consent form templates to be used by investigators for along with instructions, template language and examples to be used as a reference source. This section also includes a tool kit containing the Investigator Handbooks and PowerPoint presentation regarding How to Determine Which Application to Use, as well as a Glossary of Terms.
5. Roles and Responsibilities details the role of the Human Protection Program and its Committee's, the Investigator, study staff and the Department Chair or Center Director.
6. Participant Page includes current information related to participating in a research study, as well as resources for research participants.

7. Links includes the following:
 - IRB Committee Log In
 - SUBMIT – DISCOVER-E
 - DISCOVER-E How to
 - CITI Training
 - Workshops
 - Frequently Asked Questions (FAQs)
 - Research News at Vanderbilt
 - Performance Metrics
 - HRPP Intranet
 - HRPP Informatics
 - General Announcements & Tips
 - Office for Human Research Protections (OHRP)
 - Food and Drug Administration (FDA)
 - Family Educational Rights and Privacy Act (FERPA)
 - IRBshare
8. Blogroll includes the following:
 - AAHRPP Advance
 - OHRP on YouTube
 - PRIM&R's Ampersand
9. MedWatch provides a link to the FDA's Safety Alert RSS Feed

E. HRPP Brochures

1. *"Are You Conducting Human Subjects Research?"* This brochure targets Investigators and Key Study Personnel to provide basic information about the IRB process including:
 - The role of the IRB;
 - Definition of research and human subject;
 - Requirements for conducting research involving humans at VU;
 - Types of IRB review;
 - Requirements when performing research at other sites;
 - Definition of informed consent, required elements, and additional elements; and
 - Resources for additional information.
2. *"HIPAA and Research."* This brochure is a quick reference guide for VUMC Investigators and Key Study Personnel, and includes the following information:
 - A description of HIPAA;
 - A list of direct identifiers;
 - HIPAA rules in regards to research involving humans;
 - Tracking of disclosures; and
 - Website addresses for additional information.
3. The HRPP may send mass e-mail notifications limited to a mailing list of all active Investigators and Key Study Personnel to alert them of pertinent human subject issues or decisions affecting them. The HRPP maintains a department blog that is updated regularly to

keep the research community abreast of important developments related to human subjects research.

IV. COMMUNITY OUTREACH PROGRAMS

A. Participant Brochure

1. A Participant brochure entitled, “Your Rights as a Research Volunteer” has been developed and includes the following:
 - A lay definition of research and research personnel;
 - A description of an IRB and its role;
 - What information should be made available in an informed consent;
 - Research Participant’s Bill of Rights; and
 - Who to contact for questions concerning participation in a research study.
2. New Student Orientation Sessions: The HRPP staff and when available Committee members will attend orientation sessions for new graduate and medical students for the purpose of providing materials designed to inform students about which activities are required to be reviewed and approved by the IRB prior to initiation. The orientation sessions are held annually, in the fall, as students are arriving and becoming familiar with requirements for completion of their program.
3. Meetings with Departments and Faculty: As part of providing education to the VU and VUMC community, the HRPP staff contact faculty and department chairs to request time to meet with faculty and students to discuss involvement of human subjects in research and what requires IRB review. It is a goal of the IRB to place an emphasis on this outreach in order to educate those who may be unaware that their activities require IRB review.
4. Local Community Presentations: The HRPP staff attend functions in the local community to help promote awareness of activities conducted by the IRB in regards to protecting subjects who participate in research. These activities consist of passing out information about rights of research volunteers and/or conducting presentations throughout the community that focus on enrollment in research studies and participant’s rights once they agree to take part in a study.
5. Suggestion Box: The HRPP website provides a vehicle for the VU and VUMC research community to request or respond to specific issues of concern to the individual Investigator or key study personnel. If no response from the IRB is necessary, these comments may be submitted anonymously. However, the inquirer may request a response from the IRB by including his or her email address in the submission.
6. IMPACTT: The Vanderbilt Institute for Clinical and Translational Research offers a quality improvement program called IMPACTT (Individualized Measured Performance and Collaborative Training Techniques) which is designed to assist investigators in human subject’s research by providing study-specific consultation. IMPACTT is a free and efficient way to receive feedback regarding the conduct and implementation of your study. These goals of IMPACTT are to: assist the research team in identifying strengths and weaknesses, to provide education, and to make recommendations for improvement. Investigators interested

in initiating this process may submit a request by emailing Research.Support.Services@vanderbilt.edu.

7. Project PROTECT: The goal of project PROTECT is to provide 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 with well-integrated, electronically-linked/trigger decision support tools to use at the time of IRB proposal development, it will improve the quality of IRB applications and the protection of human participants. This enhancement will help to 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, 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.

B. Additional Vanderbilt University Outreach Programs

- Junior League Family Resource Center;
- Maternal-Infant Health Outreach Program;
- Tennessee Lion's Program;
- Vanderbilt Ingram Cancer Center-Cancer Outreach;
- Neonatal Outreach Program;
- Patient Affairs; and
- Peabody Research and Outreach.