3.0 PURVIEW and TRAINING

3.1 OBJECTIVE

To describe the institution's programs for ensuring that all Institutional Review Board (IRB) members and the Office of Regulatory Research Compliance (ORRC) staff are appropriately educated about the regulatory requirements and ethical considerations for the protection of human subjects involved in research.

3.2 GENERAL DESCRIPTION

The foundation for the effective implementation of all facets of the Howard University (HU) Human Research Protection Program (HRPP), and for efforts to promote compliance with HRPP requirements lies in a comprehensive, mandatory education program for all applicable personnel, including IRB members and research support staff in the ORRC. HU has a multifaceted human subjects' protection education program designed to provide essential training on ethics and regulations of research and local IRB policies/procedures as explained below.

3.3 RESPONSIBILITY

Execution of SOPP: IRB members and Office of Regulatory Research Compliance (ORRC) staff.

3.4 PROCEDURES

3.4.1 Initial Education for IRB Members

Following appointment to membership on the IRB and prior to serving as reviewers, IRB members, *ex officio* members, and alternate members receive the following training.

- ORRC staff provides new IRB members with a training binder titled "Howard University IRB Member Orientation".
- The ORRC also offers an Orientation session for each new member.
- ORRC Director assigns new IRB members a mentor who is an experienced IRB member to guide the new member in his/her reviews of protocols, understanding of IRB policies and procedures, and federal, state, and University regulations.
- Upon initiation of an IRB member's assignment as an expedited reviewer for new proposals, designated ORRC staff makes available a one-on-one

orientation to educate first-time reviewers on expedited applicability criteria and categories, criteria for IRB approval, and general responsibilities as an expedited reviewer.

- Upon initiation of an IRB member serving for the first time as reviewer of protocols undergoing expedited continuation review, designated ORRC staff makes available a one-on-one orientation to educate him/her on the criteria for IRB approval, applying the expedited applicability criteria, and general responsibilities as an expedited continuation reviewer.

- Upon initiation of an IRB member's assignment as exemption reviewer, designated ORRC staff makes available a one-on-one orientation to educate first-time reviewers on applying the exempt categories, and general responsibilities as an exemption reviewer.

- The University requires all IRB members to be trained in the protection of human subjects. Members may meet this requirement by:
  - Successful completion of the Public Responsibility in Medicine and Research (PRIM&R) Ethical Oversight of Human Subjects Research on-line IRB assessment and certification.
  - Complete assigned reading of the IRB member review handbook.
  - Successful completion of other designated options (e.g. Collaborative Institutional Training Initiative (CITI) on-line training.
  - Review all the archived videos on the OHRP website: http://www.youtube.com/view_play_list?p=5965CB14C2506914
  - For continued education, Copies of the Dunn and Chadwick's *Protecting Study Volunteers in Research* book will be made available to IRB members as a useful reference guide.
  - Additional materials or website links include: 45CFR46: Protection of Human Subjects (OHRP); 21CFR50: Protection of Human Subjects (FDA); 21CFR56: Institutional Review Boards (FDA);

- In addition to the above training, members receive the following educational materials per website links:
  - Howard University IRB Survival Toolkit, which includes ORRC/IRB SOPPs, HU IRB guidance, policy, and educational materials, and IRB forms.
  - Howard University IRB Resource Guide: Continuous collection of up-to-date regulations and guidelines by ORRC staff (including sections on Ethics of Human Subjects Research, Basic IRB Regulations, Selected Auxiliary Regulations/Policy, IRB Review Mechanisms, Educational Materials and other useful references).
  - ORRC website and contact information.

3.4.2 Continuing Education of IRB Members

ORRC staff offer the following continuing education opportunities to current members of the IRB.

- Ongoing Protocol Specific Training (PST): ORRC staff disseminates materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e., gene therapy or tissue banking) or selected vulnerable subject populations (i.e., prisoners) to each IRB member. In the agenda or expedited review packet, ORRC staffs refer IRB reviewers to pertinent PST materials (e.g., if a research project involves children, ORRC staff refers the reviewers to the PST materials on children).

- Exempt/Expedited: IRB members serving as expedited reviewer or exempt reviewer receive specific guidance documents for the type of review upon initiation of his/her assignment.

- IRB Members E-mail Lists: The ORRC maintains e-mail distribution lists which are used on an ongoing basis to send IRB members a variety of materials such as copies of pertinent articles, regulatory updates, web references to resource materials or government reports, or communication about a specific protocol review. The few IRB members who do not have e-mail receive paper copies of this material.

- Presentations: Upon request or as appropriate, the ORRC presents training on selected topics or invites a specialist in a specific area to address the IRB.

- Dissemination of Articles or Educational Materials Collected at Professional Meetings or from Scientific Literature: Periodically, ORRC staff includes copies of these materials in the IRB agenda packet. Also, the ORRC sends correspondence to the IRB members periodically informing them that the materials are available upon request.

- ORRC subscribes to and distributes to IRB members a variety of publications.

- ORRC staff review, update, and distribute information in the IRB Survival Toolkit and Resource Guide, as necessary.

- Every three (3) years, IRB members must become re-certified in human subjects' protection training. The CITI on-line human subjects' protection training program offers a continuing education program which satisfies this requirement. Other options are also available.

- HU will provide funds to send one each of the Medical-IRB and the Nonmedical-IRB to attend the yearly national or regional IRB conference.

3.4.3 Initial Education for New ORRC Staff

- New ORRC staff members receive the ORRC Staff Orientation Checklist as a baseline orientation guide. New staff members check each section upon completion and provide a copy of the completed checklist to the Director as documentation.

- New ORRC staff members will receive the following educational materials or website links:
  - 45CFR46: Protection of Human Subjects (OHRP);
  - 21CFR50: Protection of Human Subjects (FDA);
  - 21CFR56: Institutional Review Boards (FDA);
  - FDA Information Sheets;
  - HU ORRC website;
  - IRB Survival Handbook (includes SOPPs, guidance documents and educational materials);
  - Protocol Specific Training materials included in the IRB Survival Handbook;
  - IRB Resource Guide; and
  - HIPAA Educational Module.

- The ORRC Director in collaboration with other staff members will establish and implement a training plan for each new ORRC staff member, which includes direct hands-on training by designated experienced staff members.

- The ORRC Director will provide new ORRC staff with the ORRC Staff Operations Manual. The manual includes general information and task specific step-by-step instructions, flow charts, and checklists which allow the new staff member to double check his/her work. The manual is also used by experienced staff when conducting direct hands-on training.

- New ORRC staff members must read all existing ORRC/IRB standard operating policies and procedures.

- HU requires that all ORRC staff be trained in the protection of human subjects. ORRC staff may meet this requirement by one of two means:
  - Successful completion of the Collaborative IRB Training Initiative on-line human subjects' protection training program; or
  - Successful completion of the Dunn & Chadwick *Protecting Study Volunteers in Research* training book and on-line assessment and certification.

- New ORRC staff will complete the on-line PRIM&R Ethical Oversight of Human Subjects Research training.

3.4.4 Continuing Education of ORRC Staff

- The Associate Vice President (AVP) for Regulatory Research Compliance (RRC) holds staff meetings approximately bi-weekly but at least monthly, and half-day/full-day ORRC planning meetings one to two times a year. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an ongoing basis at these meetings. The ORRC Director periodically provides training on selected topics. Also, experts in specific areas provide specialized training on specific topics (e.g., bio and occupational health safety) at staff meetings. Periodically, ORRC staff members give presentations on selected issues/topics/conferences at staff or planning meetings.

- The ORRC encourages and periodically requires its staff members (professional and clerical) to attend University, city, state, national, or regional IRB teleconferences, workshops or lectures.

- ORRC staff receives all of the materials distributed to IRB members. Also, staff receives copies of selected compliance information/material distributed by the ORRC Director or senior staff (e.g., Office for Human Research Protections [OHRP] publications such as the Engagement Memo, copies of innovative materials used by other IRBs/institutions, Food and Drug Administration [FDA] and OHRP correspondence, training materials developed by external groups, PRIM&R Board educational e-mails).

- If during the year designated ORRC staff revise Standard Operating Policies and Procedures (SOPPs) or add information to an SOPP, and the SOPP is subsequently approved/signed by the AVP for RRC (and when applicable, other individuals, e.g., SOPPs for coordination between units), ORRC staff is notified by the ORRC Director upon implementation of the approved/signed revised SOPP.

- Every three (3) years, ORRC staff must become re-certified in human subjects' protection training. The CITI Web-based human subjects' protection training program offers a continuing education program to satisfy this requirement. Other options are available.

- New ORRC staff (Compliance level) will be required to complete the Certification Examination for IRB Professionals (CIP) within 12 months of hire, and subsequently, maintain certification. Current ORRC staff (Compliance level) will be required to attend training and complete the CIP within 12 months of the approval of this policies and procedures.

- At least one ORRC staff (Compliance level) member will attend the yearly national or regional PRIM&R conferences.