

SOP# HRP 04.02
Approval Date: 4/10/08

RESEARCH PERSONNEL – Mandatory Trainings

OBJECTIVES

- Principal investigators and key research personnel have completed and can document initial and continuing training in Human Research Protections.
- VA R&D Committee and subcommittee members (i.e. Human Studies Subcommittee and Human Research Protection & Oversight Committee) must have completed and can document initial and continuing training in Human Research Protections.

BACKGROUND

No Human research Protection Plan (HRPP) can be implemented unless investigators, research staff, research team members and committee/subcommittee members have a knowledge of human subject protections. They must also have an understanding of the ethical and regulatory foundations of human research subject protections in order to promote adherence to principles, rules and regulations. This requires a multilevel approach:

1. basic education about research ethics and human subject protection,
2. specific knowledge about the VAMHCS Human Research Protection Program (HRPP),
3. continual and periodic updates on changes in the HRPP, VA regulations, federal and state regulations, UMB IRB policies and procedures, and other institutional changes.

RESPONSIBILITIES

Principal investigators are responsible for ensuring that they and their staff have completed the VA annual training requirements.

VAMHCS R&D Committee and subcommittee members are responsible to complete their annual mandatory trainings.

The VAMHCS Research Service administrative staff: is responsible for maintaining the trainings database for VAMHCS research staff and committee/subcommittee members.

POLICY

1. All principal investigators, key research personnel, VA R&D Committee and subcommittee members involved in human participants research are required to complete annual* trainings in privacy, Good Clinical Practices, human subjects protections and data security. The current requirements are posted on the Research Service website:
<http://www.maryland.research.va.gov/training.asp>.
2. Principle investigators must provide proof of completion of required trainings for themselves and their staff in order to submit protocols to the R&D Committee. A Research Service database that tracks these requirements is updated by administrative staff as training certificates are submitted.
3. On occasion, there may be other trainings or continuing education sessions required by the Research Service, the VHA, the UMB HRPO, or other agencies.
4. Principle Investigators and staff are required to be knowledgeable about Research Service and HRPO SOPs.

PROCEDURES:

- 1 Mandatory training:
Current information on mandatory trainings is found on the Research Service "Training/Education" webpage,
<http://www.maryland.research.va.gov/training.asp>.
- 2 Continuing or newly required education and trainings:
 - The Research Service sends email communications to the VAMHCS research community to notify them of new or changed Research Service SOPs and/or new training requirements or continuing education sessions. The UMB HRPO sends email notices of new or changed HRPO policies and procedures.
 - Research Service SOPs are available through the Research Service webpage, "Human Subject Standard Operating Procedures (SOPs)",
http://www.maryland.research.va.gov/research/human/human_subject_sops.asp.

* VA employee trainings expire on the last day of the fiscal year (9/30), regardless of when the training was completed during the fiscal year; WOC employee trainings expire at the anniversary dates of their courses.

- The Research Service sends “Research Service Hot Topics” on an approximate bi-weekly schedule as a method of updating research staff on policy changes and other topics. These Hot Topics are archived on the Research Service website.
 - UMB Human Research Protections Office (HRPO) SOPs are available through the HRPO webpage, “HRPO Policies & Procedures”, <http://medschool.umaryland.edu/orags/hrpo/policies.asp>. Investigators and staff who wish to familiarize themselves with HRPO policies and procedures thus have access to them at all times.
 - The HRPO presents monthly “Research Round Table” sessions for continuing updates.
- 3 Compliance:
- 3.1. The investigator and key research personnel must be current in their annual trainings before a protocol may be submitted to the R&D Committee review process or annual update process. The investigator submits confirmation of staff training at the time that the protocol is submitted for R&D Committee approval or annual update. If the investigator or study staff are not current with their annual trainings, the R&D Coordinator holds the protocol from the R&D process until verifications of trainings have been obtained.
 - 3.2. Any new members of the research team must meet at least Policies 1-2 above before they can be approved to conduct research activities. The modification request submitted by the PI for this purpose will not be approved until Policies 1-2 have been met.
 - 3.3. All research team members, their training status and the status of their scope of practice will be entered into a Research Service database.

APPROVAL

This SOP entitled “Research Personnel Training” has been approved by the Medical Center Director, effective 4/10/08.