

Research Personnel Training – P 1 of 3
 VAMHCS HUMAN RESEARCH PROTECTION
 STANDARD OPERATING PROCEDURE

SOP# HRP 04.02

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RESEARCH PERSONNEL – Mandatory Trainings

OBJECTIVES

- Principal investigators and research personnel engaged in VA research have completed and can document initial and continuing training in Human Research Protections, Good Clinical Practices (optional) and other trainings required by VHA & VAMHCS.
- VAMHCS R&D Committee and subcommittee members must be able to document completion of initial and continuing training in Human Research Protections trainings and other trainings required by VHA & VAMHCS.

BACKGROUND

No Human Research Protection Plan (HRPP) can be implemented unless investigators, research staff, research team members and committee/subcommittee members have 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.

POLICY & SCOPE

1. All principal investigators, key research personnel, VA Research & Development Committee (RDC) and subcommittee members involved in human participants research at the VAMHCS are required to complete trainings in human subjects protections, , privacy, and data security as required by VA regulations. The current requirements are posted on the Research Service website: <http://www.maryland.research.va.gov/training.asp>.
2. This SOP applies only to the trainings required by VA ORD, VA Privacy Office, and VA Office of Information & Technology for the general purpose of conducting human subjects research. VA or the VAMHCS may require additional trainings as applicable to specific roles and responsibilities of individuals (for example, laboratory safety trainings, infection control trainings, “Slips and Falls” training, etc.). These additional trainings are not within the scope of this SOP.
3. The requirement for human research protections trainings applies to all individuals involved in the conduct of VA human subjects research regardless of pay status, appointment type (title 38, title 5, IPA, or WOC), and length of time at the VA facility, including, but not limited to:

investigators, study coordinators, research assistants, other members of the research team, trainees, such as house officers and students, all members of the research office whose responsibilities include involvement with human research (e.g., the ACOS for R&D and the AO for R&D), VA representatives to the UMB IRB, all voting, and ex officio, nonvoting members of the R&D Committee, and members of other research committees or subcommittees that review research involving human subjects. This training requirement also applies to investigators and research team members conducting studies involving human subjects that are exempt from IRB review, as well as those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent.

4. This training requirement does not apply to secretarial support staff or research office staff whose responsibilities do not involve human research (e.g., those who deal only with research involving animals).
5. Principal investigators must be current in their required trainings in order to submit protocols to the RDC.
6. Principal investigators are responsible for ensuring that their team members are current in required trainings.
7. On occasion, there may be other research trainings or continuing education sessions required by the Research Service, the VHA, the UMB HRPO, or other agencies.
8. Trainings are documented through the VA Talent Management System (TMS) or the CITI system.
9. Principal Investigators and staff are required to be knowledgeable about R&D Service and HRPO SOPs. R&D Service and HRPO policies are available on their respective websites.

RESPONSIBILITIES

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

VAMHCS Research & Development Committee (RDC) and subcommittee members are responsible for completing their annual mandatory trainings.

The VAMHCS Research & Development (R&D) Service administrative staff: are responsible for ensuring that VAMHCS research staff and committee/subcommittee members are current in their mandatory trainings.

PROCEDURES:

- 1 Mandatory training:

Current information on mandatory trainings to conduct VA human subject research 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.
 - Research Service SOPs are available through the R&D Service webpage, "Human Subject Standard Operating Procedures (SOPs)", http://www.maryland.research.va.gov/research/human/human_subject_sops.asp.

- The Research Service sends “Research Service Hot Topics” as a method of updating research staff on policy changes and other topics. These Hot Topics are archived on the Research Service website, http://www.maryland.research.va.gov/hot_topics.asp.
 - The Research Service conducts “Brown Bag” sessions as informal opportunities for the research community to obtain information, ask questions, and give suggestions.
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 - UMB Human Research Protections Office (HRPO) SOPs are available through the HRPO webpage, “HRPO Policies & Procedures”, <http://www.hrpo.umaryland.edu/policies.asp>.
- 3 Compliance with this SOP:
- 3.1. The principal investigator must be current in his/her annual trainings before a protocol may be submitted to the R&D Committee review process or annual update process. If the investigator is not current with required trainings:
 - 3.1.1. The R&D Coordinator may hold the protocol from the R&D process until verifications of trainings have been obtained;
 - 3.1.2. The protocol may be placed on administrative hold until trainings are completed;
 - 3.1.3. The Privacy Office may deny access to CPRS.
 - 3.2. The training status of the study’s VA research team may be evaluated during regulatory audits conducted by the Office of Research Compliance. If VA team members are not current with required trainings:
 - 3.2.1. The team member(s) may be placed on administrative hold for VA duties until trainings are completed;
 - 3.2.2. The Privacy Office may deny access to CPRS.