

**Research Program Policy & Procedure
Education for Conducting Research****Education Requirements for the Conduct of Research**

1. **PURPOSE:** To establish a service level policy identifying the educational requirements for conducting research at the Portland VA Medical Center (PVAMC). This policy will help to ensure the protection of all human research participants, animal research subjects, and the safety of research personnel and promote ethical standards of human and animal research.
2. **POLICY:** All individuals working in PVAMC research are required to complete an education program consistent with Department of Veterans Affairs regulations. The R&D Service Office will monitor completion and annual renewal of educational requirements except where otherwise noted.
 - a. **All Research Personnel** with VA-paid or Without Compensation (WOC) appointments, the Medical Center Director, the Chief of Staff, the Research Compliance Officer, *voting and ex officio* members of the Research and Development Committee (R&DC), and *voting and ex officio* members of PVAMC research subcommittees (IRB, Safety, IACUC, Space) must complete
 - **Information Security 201 Training for Research and Development Personnel.** This training is required only once (prior to appointment). No annual training is required.
 - **Privacy and HIPAA Training.** This training is required prior to appointment and yearly thereafter.
 - **VA Privacy and Information Security Awareness and Rules of Behavior.** This training is required prior to appointment and yearly thereafter.
 - b. **Research Personnel Involved in PVAMC Human Research (including human research that has been certified Exempt from IRB review)** who
 - will interact with participants, and/or
 - will see identifiable data, and/or
 - are members of the IRB or the R&DC (*voting and ex officio*), or
 - are R&D Service staffmust also complete **The Collaborative Institutional Training Initiative (CITI) “Basic Course in the Protection of Human Subjects”** prior to appointment and once every two years, i.e. within 730 days of the previous training thereafter.
 - Research personnel who conduct, review, approve, oversee, support or manage human participant research that will follow a Department of Defense (DOD) Addendum, must meet any specific initial and continuing educational requirements or certification required by the DOD. R&D staff delegated by the ACOS/R&D to submit the FWA will notify IRB staff, IRB chair and members, investigators and research staff of any additional educational requirements.

**Research Program Policy & Procedure
Education for Conducting Research**

- c. **Research Personnel with access to PVAMC research areas**, e.g., those working in labs or other research areas, must also complete **General Safety Training**. This training must be taken prior to appointment and yearly thereafter.
- d. **Research Personnel Working in Wet Labs** must also complete **Biosafety Training** prior to appointment and yearly thereafter.
- e. **Research Personnel Working with Radiation** must also complete **Radiation Safety Training** prior to appointment and yearly thereafter.
- f. **Research Personnel Involved in PVAMC Animal Research** who
 - participate in or supervise animal procedures conducted at the PVAMC, and/or
 - work with animals purchased with VA funds regardless of performance location, and/or
 - work with animals during VA duty hours regardless of location,must also complete the following **CITI courses** prior to appointment and once every two years, i.e. within 730 days of the previous training:
 - **“Working with the IACUC” (Institutional Animal Care and Use Committee)**
 - **Appropriate species-specific courses** (e.g., “Working with Mice in Research Settings,” Working with Rats in Research Settings”)Staff of the Veterinary Medical Unit may receive other training appropriate for their responsibilities and consistent with the training commitments in both the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Program Description and Public Health Service Assurance.
- g. **IACUC Members and IACUC Support Staff** must also complete **the CITI course “Essentials for IACUC Members”** prior to appointment and once every two years, i.e. within 730 days of the previous training.

3. RESPONSIBILITIES and PROCEDURES: In addition to meeting their own training requirements, officials and staff are responsible for the following:

- a. The Medical Center Director is required to fulfill all educational requirements mandated by the VA Office of Research and Development and OHRP.
- b. The **Associate Chief of Staff / Research & Development** is responsible for developing and managing policies and procedures that ensure compliance with the educational requirements of the R&D Service.
- c. The **Administrative Officer of R&D or the Deputy Associate Chief of Staff / R&D** is responsible for implementing the educational requirement policy through the R&D Service Office.

**Research Program Policy & Procedure
Education for Conducting Research**

- d. The **Research & Development Committee (R&DC)** is responsible for reviewing and approving this policy and assuring training requirements have been met by all research personnel before approving a research study not reviewed by any subcommittees.
- e. **R&D Subcommittees (IRBs, IACUC, Safety)** are responsible for assuring training requirements have been met by all research personnel before approving a research study.
- f. The **Research Assurance Officer** is responsible for
- Developing and presenting educational programs for investigators, and research staff involved in human and animal research
 - Advising IRB and R&D committee members, ACOS and Deputy ACOS/R&D, AO/R&D, R&D investigators and research staff about state, VA and other federal regulations as needed to assure compliance.
- g. The **IRB Analysts** are responsible for
- Providing training for IRB Chairs and members prior to appointment and during their tenure on the IRB.
- h. The **Research Compliance Officer** is responsible for auditing all research and reporting any training deficiencies found during an audit to the ACOS/R&D, appropriate R&D Subcommittees and the R&D Committee.
- i. **Principal Investigators** are responsible for
- Submitting documentation of successful completion of educational requirements initially and annually to the R&D Office.
 - Ensuring all individuals involved in their studies have completed all required training.
- j. **Research Employees and other Medical Center Staff** participating in approved research projects are responsible for submitting documentation of successful completion of educational requirements to the R&D Office.

4. REFERENCES: Department of Veterans Affairs, Office of Research & Development “Required Training for VA Researchers” at <http://www.research.va.gov/training/default.cfm>. VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research.

5. CONCURRENCES: Endorsed by the R&D Committee 12/06/2010.

6. RESCISSION: HRPP: Education for the Protection of Human Research Participants Conducting Research in the Research & Development Service, endorsed by the R&D Committee 06/10/2002, 06/16/2003, 11/24/2003, 05/03/2004, 06/28/2004, 05/02/2005, 08/27/2007, 05/04/2009 04/05/2010, and 12/6/2010.

7. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

VA MEDICAL CENTER, PORTLAND, OREGON
Research Program Policy & Procedure
Education for Conducting Research

Effective: 01/09/2012

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service