

EDUCATION REQUIREMENTS FOR THE CONDUCT OF RESEARCH

- 1.PURPOSE:** To establish a service level policy identifying the educational requirements for conducting research at the VA Portland Health Care System (VAPORHCS). This policy will help to ensure the protection of all human research participants and animal research subjects and the safety of research personnel, and to promote ethical standards of human and animal research.

- 2.POLICY:** All individuals working in VAPORHCS research are required to complete an education program consistent with Department of Veterans Affairs regulations. The Research & Development (R&D) Administration Office will monitor completion and renewal of educational requirements, except where otherwise noted.
 - a. **All Research Personnel** with VA-paid or Without Compensation (WOC) appointments, the Health Care System 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 the research subcommittees [i.e. Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), Institutional Animal Care and Use Committee (IACUC), Research Service Space Subcommittee (RSSS)] must complete the following, which are all **required** prior to appointment and yearly thereafter:
 - **Privacy and HIPAA Training**
 - **Government Ethics Training**
 - (1) Exception: Non-hybrid Title 38 employees with a clinical occupation code and coded as either Part Time (Employee Status 2) or Intermittent (Employee Status 3) are considered Transient Clinical Staff. These employees are required to complete **Mandatory Training for Transient Clinical Staff**, which covers the two trainings listed above.
 - **VA Privacy and Information Security Awareness and Rules of Behavior**

 - b. **Research Personnel Involved in VAPORHCS 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 or *ex officio*), and/or
 - are VA representatives to external IRBs (e.g., affiliated academic institutions), and/or
 - are members of the R&D Administration Office and their responsibilities include involvement with human research,must also complete:
 - the initial **Collaborative Institutional Training Initiative (CITI) Human Subjects Protection course** prior to appointment and then the required CITI Human Subjects Protection refresher course once every three years thereafter; or

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- the human subjects training course required by Oregon Health and Science University, including any VA-specific portions listed, prior to appointment and then the related renewal course(s) once every three years thereafter.

In addition, research personnel who conduct, review, approve, oversee, support or manage human 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 Federal Wide Assurance (FWA), will notify IRB staff, IRB chairpersons and members, investigators and research staff of any additional educational requirements.

c. **Research Personnel with access to VAPORHCS 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 VAPORHCS Animal Research**, who:

- participate in or supervise animal procedures conducted at the VAPORHCS, 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 three years thereafter:

- **“Working with the IACUC,”** and
- **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 Coordinators** must also complete **the CITI course, “Essentials for IACUC Members,”** prior to such appointment and once every three years thereafter.

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

- a. The **Health Care System Director** is required to fulfill all educational requirements mandated by the VA Office of Research and Development and the Office for Human Research Protections.
- b. The **Associate Chief of Staff/R&D** 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/R&D or the Deputy Associate Chief of Staff /R&D** is responsible for implementing the educational requirement policy through the R&D Administration Office.
- d. The **R&D Committee (R&DC)** is responsible for reviewing and approving this policy and assuring training requirements have been met by all research personnel before initially approving a research study that is not reviewed by any subcommittees.
- e. **R&D Subcommittees (e.g. IRB, IACUC, SRS)** are responsible for assuring that applicable training requirements have been met by all research personnel before initially approving a research study.
- f. The **Research Assurance Officer** is responsible for:
 - developing and presenting educational programs for investigators and research staff, and
 - advising committee and subcommittee members, ACOS/R&D, 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 IRB-specific training for IRB Chairs and members prior to IRB appointment and during their tenure on the IRB.
- h. The **IACUC Coordinators** are responsible for providing IACUC-specific training for IACUC Chairs and members prior to IACUC appointment and during their tenure on the IACUC.
- i. The **SRS Coordinators** are responsible for providing SRS-specific training for SRS Chairs and members prior to SRS appointment and during their tenure on the SRS.
- j. 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 subcommittees and R&DC.
- k. **Principal Investigators** are responsible for:

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- submitting documentation of successful completion of educational requirements, initially and as required thereafter, to the R&D Administration Office, and
- ensuring that all individuals involved in their studies have completed all required training.

I. Research Employees and other Medical Center Staff participating in approved research projects are responsible for submitting documentation of successful completion of educational requirements, initially and as required thereafter, to the R&D Administration Office.

4. REFERENCES:

- a. Department of Veterans Affairs, Office of Research & Development, Training Requirements for Human Subjects Protection webpage (<https://www.research.va.gov/pride/training/default.cfm>)
- b. Department of Veterans Affairs, Privacy Office, Training webpage (<https://vaww.vets.vaco.portal.va.gov/sites/privacy/vhapo/Pages/training.aspx>)
- c. VA Directive 6500, Managing Information Security Risk: VA Information Security Program (https://www1.va.gov/vapubs/search_action.cfm?dType=1)
- d. VHA Directive 1200.02, Research Business Operations (http://vaww.va.gov/vhapublications/publications.cfm?Mode=CURRENT&pub=2&order=asc&orderby=pub_Number)
- e. VHA Directive 1605.01, Privacy and Release of Information (http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number)
- f. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research (http://vaww.va.gov/vhapublications/publications.cfm?Mode=CURRENT&pub=2&order=asc&orderby=pub_Number)

5. CONCURRENCES: Endorsed by the R&D Committee on 08/28/2017.

6. RESCISSION: Research Program Policy & Procedure “Education Requirements for the Conduct of Research,” endorsed by the R&DC on 03/07/2016.

7. FOLLOW-UP RESPONSIBILITY: ACOS/R&D

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