

**EDUCATION FOR THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS
IN THE RESEARCH & DEVELOPMENT SERVICE**

1. **PURPOSE:** To establish a service level policy that identifies the individuals required to complete the educational requirements in the protection of human research participants and the educational programs that meet these requirements. This policy will help to ensure the protection of all human research participants and promote ethical standards of human research performed at the Portland VA Medical Center (PVAMC).

2. **POLICY:** All individuals responsible for the protection of human subjects in research at the PVAMC are required to complete an education program in the protection of human research participants, consistent with the requirements of the Department of Veterans Affairs regulations,. This includes, but is not limited to the Associate Chief of Staff, R&D; Administrative Officer, Research & Development (R&D); Research & Development(R&D) Committee members and alternates; Institutional Review Board (IRB) members and qlternates; IRB Coordinators; Research Assurance & Compliance Coordinator (RACC); all principal investigators involved in human subjects research; all co-principal Investigators, co-investigators; and all other research and/or medical personnel involved in any PVAMC IRB-approved research projects. This includes individuals who see and/or handle identifiable VA patient human biological specimens and/or identifiable VA patient data, and/or have direct research-related contact with VA patients participating in research.

Consistent with VA policy, all individuals must initially successfully complete the two following education modules:

- a. Collaborative Institutional Training Initiative -Basic Course in the Protection of Human Subjects and
- b. PVAMC Education in the Protection of Human Research Participants.

Re-training is required annually, specifically on a 365-day basis, and requires successful completion of only the CITI module. The above stated program encompasses the Veterans Health Administration (VHA) Office of Research & Development (ORD) educational requirements. All involved personnel must complete and submit documentation of this educational requirement prior to final study approval by the IRB and prior to participating in IRB- approved research projects. The R&D Service Office will monitor completion and annual renewal of educational requirements.

Other required training modules for all research staff include the following:

- a. VA Research Data Security and Privacy
- b. VA Cyber Security Awareness
- c. VHA Privacy Policy HIPAA

Modules that may be required if applicable, but are not part of the HRPP include the following:

- a. General Safety Training
- b. Radiation Safety Training
- c. Biosafety Training

3. RESPONSIBILITIES and PROCEDURES:

- a. The **Associate Chief of Staff / Research & Development (ACOS/R&D)** is responsible for the following:
 - (1) developing and managing policies and procedures that ensure compliance with the educational requirements of the R&D Service;
 - (2) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants; and
 - (3) completing the CITI educational requirement in the protection of human subjects in research training annually.

- b. The **Administrative Officer (AO) of R&D** is responsible for the following:
 - (1) implementing the educational requirement policy through the administrative office of R&D Service.
 - (2) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants; and
 - (3) completing the CITI educational requirement in the protection of human subjects in research training annually.

- c. The **Research & Development Committee (R&D) Members** are responsible for the following:
 - (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants; and
 - (2) completing the CITI educational requirement in the protection of human subjects in research training annually.

- d. The **Institutional Review Board (IRB) Members** are responsible for the following:
 - (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants.
 - (2) completing the CITI educational requirement in the protection of human subjects in research training annually.
 - (3) completing other education requirements as set forth by the IRB Chair(s).

- e. The **Institutional Review Board Coordinators** are responsible for:
 - (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants.
 - (2) completing the CITI educational requirement in the protection of human subjects in research training annually.
 - (3) verifying that all Principal Investigators submitting new and continuing reviews of protocols involving human research participants, human biological specimens and/or human data have successfully completed the required training prior to final IRB study approval.
 - (4) verifying that all Co-Principal Investigators, Co-Investigators, and all other research and/or medical personnel participating on an IRB approved research project have successfully completed the required training prior to final IRB study approval. This includes individuals who handle identifiable VA patient human biological specimens,

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- identifiable VA patient data, and/or have direct research related contact with VA patients participating in research.
- (5) notifying investigators and staff when educational requirements in the protection of human research participants need to be renewed.
 - (6) maintaining educational requirements for the Protection of Human Research Participants in the Personnel Database for all individuals involved in human subjects research.
 - (7) informing the IRB during initial or continuing reviews when some necessary research personnel have not completed the appropriate education in the protection of human research participants. Such projects may only be contingently approved until the appropriate education is completed.
 - (8) alerting the IRB to the possible need for suspending research projects involving human research in which necessary personnel have not completed the appropriate education in the protection of human research participants.
- f. The **Research Assurance and Compliance Coordinator** is responsible for:
- (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants;
 - (2) completing the CITI educational requirement in the protection of human subjects in research training annually;
 - (3) developing and presenting, if applicable, educational programs for investigators and research staff involved in human subjects research; and
 - (4) educating and advising IRB and R&D committee members, ACOS/R&D, AO/R&D, R&D investigators and research staff of state, VA and other federal regulations as needed to assure compliance.
- g. **Principal Investigators**
Principal Investigators (VA employees or appointees, including those serving without compensation) who have current active IRB-approved research projects involving human research participants, human biological specimens and/or human data are responsible for the following:
- (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants.
 - (2) completing the CITI educational requirement in the protection of human subjects in research training annually.
 - (3) submitting documentation of successful completion of educational requirements prior to initial or continuing review of research project submission to the IRB, if not previously completed.
 - (4) Informing the IRB of changes of study personnel.
 - (5) Ensuring all required individuals involved in their studies have completed the above required protection of human research participants training.
- h. **Research Employees and other Medical Center Staff** participating in an IRB-approved research project are responsible for the following:
- (1) successfully fulfilling the initial educational requirement for both training modules in the protection of human research participants;

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- (2) completing the CITI educational requirement in the protection of human subjects in research training annually; and
- (3) submitting documentation of successful completion of the above educational requirements to the Research Service prior to human research participant contact.

Note: This includes individuals who handle identifiable VA patient human biological specimens, identifiable VA patient data, and/or have direct research related contact with VA patients participating in research.

i. Individuals Not Required to Complete the Education Requirements

- (1) Members of the research team who are strictly administrative staff and do not work with research participants or see identifiable information about VA research participants
- (2) Individuals who are based at an affiliate or other outside institution, and who do not come to the VA or do not directly interact with VA research participants (This does not apply to individuals who have any type of appointment at the VA: they must complete the education requirements.)
- (3) Co-investigators who do not work at the VA (e.g., a VA researcher may collaborate with researchers from outside the VA, but the VA portion of the study is conducted at the VA with VA personnel. The outside people may be co-investigators on a VA study, but if the outside researchers do not come to the VA to perform the research or enroll VA patients and do not see identifiable VA participant data, they are not required to complete these education requirements.
- (4) Outside biostatisticians (e.g., VA researchers may send de-identified data to an affiliate or other outside based statistician for processing).
- (5) Outside lab technicians (e.g., VA researchers may send de-identified VA specimens to be processed at an affiliate or other outside lab).
- (6) Members of groups such as data safety monitoring boards (DSMB) who are recruited from non-VA institutions.
- (7) Clinical personnel who periodically perform tests on research patients as part of their routine jobs (e.g., X-ray, nuclear medicine, or medical laboratory technologists who occasionally perform a test on a research patient as part of their routine clinical duties).
- (8) Individuals working with de-identified VA patient data or de-identified VA patient human biological specimens.

5. REFERENCES:

VHA Directive 2003-036, July 7, 2003, Credentials and Training of Employees Involved in Human Subjects Research
Memorandum from the Deputy Under Secretary for Health for Operations and Management, May 19, 2003
VHA Directive May 10, 2007, Requirement for credentialing of all research staff
Department of Veterans Affairs, Office of Research & Development, memorandum dated March 14, 2001

6. CONCURRENCES: Endorsed by the R&D Committee 05/02/2005

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7. RESCISSION: HRPP: Policy & Procedure No. 4, Endorsed by the R&D Committee
06/10/2002; 06/16/2003; 11/24/2003; 05/03/2004; 06/28/2004 and 05/02/2005.

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

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