

**CREDENTIALING OF PERSONNEL  
INVOLVED IN HUMAN SUBJECTS RESEARCH**

1. **PURPOSE:** To establish a service level policy that identifies the personnel who are involved in human subjects research and who must have their credentials verified and the process for verifying such credentials consistent with VA policy. This policy assures that the education, certification(s) and license(s) of all personnel involved in human subjects research will be verified and files maintained to help assure that personnel are appropriately educated, certified, and/or licensed to effectively and safely perform human subjects research at the Portland VA Medical Center (PVAMC).
2. **POLICY:** Personnel involved in human subjects research at the PVAMC must have their credentials verified, prior to working on PVAMC Institutional Review Board (IRB) approved research projects, to ensure appropriate completion of their stated education, certification(s) and license(s). Working on PVAMC IRB-approved research projects is contingent upon successful completion of credentialing requirements.
3. **RESPONSIBILITIES:**
  - a. The **Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for:
    - (1) Completing credentialing requirements, as defined by national and local policy.
    - (2) Developing and managing credentialing policies and procedures for personnel involved in human subjects research at the PVAMC.
    - (3) Ensuring that all personnel involved in human subjects research at the PVAMC have completed the appropriate credentialing requirements consistent with VA policy.
  - b. The **Administrative Officer for Research & Development (AO/R&D)** is responsible for:
    - (1) Completing credentialing requirements as defined by national and local policy with the exception of the Scope of Work Form.
    - (2) Overseeing the Research Service staff involved with the credentialing of personnel involved in human subjects research.
  - c. The **Research and Development Committee (R&D) Members** are responsible for completing credentialing requirements, with the exception of the Scope of Work Form.
  - d. The **Research and Development Committee (R&D) Coordinator** is responsible for completing credentialing requirements.
  - e. The **Institutional Review Board Members** are responsible for completing credentialing requirements with the exception of the Scope of Work Form.
  - f. The **Institutional Review Board Coordinators** are responsible for:
    - (1) Completing credentialing requirements.
    - (2) Prior to IRB review, forwarding new research project proposals to the Research Assurance & Compliance Coordinator (RACC) in order to assure that all personnel on the project have successfully completed the credentialing requirements.
    - (3) Only forwarding new research project proposals to the IRB for which the RACC has determined that all necessary staff have successfully completed the credentialing requirements.
  - g. The **Research Service Human Resources Liaison** is responsible for:

- (1) Validating the education, certification(s), and/or license(s) as reported on the Education Verification Form or VA Employee Application(s) for personnel involved in human subjects research at the PVAMC.
- (2) Monitoring personnel compliance with the credentialing requirements.
- (3) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with credentialing requirements.
- (4) On a monthly basis, downloading the Department of Health & Human Services Office of the Inspector General List of Excluded Individuals/Entities (LEIE) and printing the Food and Drug Administration and verifying whether or not any personnel who are participating on PVAMC IRB-approved research projects are on either list.
- (5) Maintaining the Human Subjects Research section of the Personnel Database.
- (6) Verifying annually that the license(s) and certification(s) of those individuals not in VetPro are still current and in good standing.

h. The **Research Service Without Compensation (WOC) Coordinator** is responsible for:

- (1) Identifying, initiating, processing and following-up with personnel who are involved in human subjects research at the PVAMC and who are required to have Without Compensation (WOC) appointments.
- (2) Monitoring personnel compliance with WOC appointments.
- (3) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with WOC requirements.
- (4) Working with Human Resources to ensure the WOC appointments are complete.
- (5) Maintaining updated WOC files.

i. **Personnel involved with PVAMC IRB-approved research projects** are responsible for completing credentialing requirements, as requested prior, to participating on PVAMC IRB-approved research projects.

#### **4. PROCEDURES:**

a. **Personnel involved in PVAMC IRB-approved human subjects research projects are required to complete the credentialing requirements.** These individuals may include PVAMC employees (Title 5 and 38), Portland VA Research Foundation Employees, Oregon Health & Science University (OHSU) employees or otherwise. A flow diagram depicting an overview of the required information is included in Appendix A. Involvement in a human subjects research project includes:

- (1) Research staff who interact with VA research participants via telephone or in person;
- (2) Research staff who collect and analyze identifiable patient laboratory specimens or patient data of participants in a VA IRB-approved study;
- (3) Research staff who perform patient laboratory tests or work with identifiable patient data of participants in VA research studies;
- (4) Research staff with a Without Compensation appointment;
- (5) Research Service staff, including: ACOS/R&D, AO/R&D, R&D Committee Coordinator, IRB Coordinators, and RACC; and
- (6) R&D Committee and IRB members.

b. **Personnel involved in PVAMC IRB-approved human subjects research projects that are NOT required to complete the credentialing requirements:**

- (1) Members of the research team who are strictly administrative staff, e.g. receptionist, including any individuals that may have contact with a patient for scheduling purposes only.
- (2) People 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 or their identifiable specimens or data.
- (3) Co-investigators who do not do work at the VA. A VA researcher may collaborate with researchers from outside the VA, but the VA portion of the study must be conducted at the VA by VA

personnel. The outside people may be co-investigators on a VA study and have their names listed on the informed consent form(s) given to VA enrollees. However, if the outside researchers do not come to the VA to perform the research or enroll VA patients, they do not need to meet credentialing requirements.

- (4) Outside biostatisticians (e.g. VA researchers may send their data to an affiliate or other outside-based statistician for processing).
- (5) Outside lab technicians (e.g., VA researcher may send VA specimens to be processed at an affiliate or other outside lab).
- (6) Volunteers from the community who serve on an IRB or R&D Committee.
- (7) Members of groups such as Data Safety Monitoring Boards (DSMBs) who are recruited from non-VA institutions.
- (8) 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). The credentials and qualifications of these individuals were validated when they were initially appointed as federal employees.

**c. Personnel credentialed in VetPro**

- (1) VetPro is the national VA credentialing system. Physicians, nurse practitioners, and other personnel (whether Title 38 Employees, fee basis or consulting and attending) with positions that require a professional license to interact with patients in a supervised setting are credentialed through this system.
- (2) Personnel who have a professional license, as necessary to interact with patients in a supervised setting, and who are typically entered into VetPro, consistent with the Medical Service Credentialing Office procedures, will be referred and credentialed through the VetPro system by the Medical Service Credentialing Office.
- (3) Personnel who have been previously credentialed through VetPro do not need to complete additional credentialing requirements outlined in this policy.

**d. PVAMC Employees involved with PVAMC IRB-approved human research projects**

**Exception: The employee is or will be credentialed through VetPro.**

- (1) PVAMC employees must complete and submit the following to the Research Service as indicated on the checklist in Appendix B:
  - (a) Scope of Work form that has been signed by the Supervisor/Principal Investigator;
  - (b) Education Verification Form for each degree, certification, or license earned; and
  - (c) Copy of Professional License (if required for interaction with patients in a supervised setting).
- (2) The Research Service will request the required information from Human Resources as detailed in Appendix C.
- (3) The Research Service will verify declared education and/or certification(s).
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) A human subjects research credentialing file for the individual will be maintained by the Research Service.

**e. PVARF Employees involved with PVAMC IRB-approved human research projects**

**Exception: The employee is or will be credentialed through VetPro.**

- (1) PVARF employee must complete and submit the following to the Research Service as indicated on the checklist in Appendix D:
  - (a) Scope of Work form that has been signed by the Supervisor/Principal Investigator;
  - (b) Education Verification Form for each degree, certification, or license earned; and
  - (c) Copy of Professional License (if required for interaction with patients in a supervised setting).
- (2) PVARF employees whose length of employment exceeds 60 calendar days must also have a WOC appointment. PVARF employees must complete and submit the following to the Research Service:
  - (a) PVARF Application Form (if not already completed);

- (b) Copy of Curriculum Vitae (if available) or resume; and
- (c) Intellectual Property Agreement.

The employee must also be finger printed by the Human Resources Division.

- (3) The Research Service will verify declared education and/or certification(s).
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

**f. OHSU Residents involved with PVAMC IRB-approved human research projects**

(1) OHSU Residents must complete and submit the following to the Research Service as indicated on the checklist in Appendix E:

- (a) Scope of Work form that has been signed by the Supervisor/Principal Investigator;
- (b) OF 612 Form;
- (c) Copy of Curriculum Vitae (if available) or resume; and
- (d) Intellectual Property Agreement.

(2) OHSU Residents who wish to have a WOC may be granted a WOC appointment. The WOC appointment will be processed through Human Resources Division. The resident must also be finger-printed by Human Resources Division.

- (3) The Research Service will request a Resident/Trainee Credentials Verification Letter (RCVL) from the Medical Service Credentialing Office for each Resident.
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

**g. OHSU Employees involved with PVAMC IRB-approved human research projects**

**Exception: The employee is or will be credentialed through VetPro.**

(1) OHSU employees must complete and submit the following to the Research Service as indicated on the checklist in Appendix F:

- (a) Scope of Work form that has been signed by the Supervisor/Principal Investigator;
- (b) Education Verification Form for each degree, certification, or license earned; and
- (c) Copy of Professional License (if required for interaction with patients in a supervised setting).

(2) OHSU employees that will be participating on a PVAMC IRB-approved research project that exceeds 60 calendar days must also have a WOC appointment. The OHSU employee must complete and submit the following to the Research Service:

- (a) OF 612 Form;
- (b) Copy of Curriculum Vitae (if available) or resume; and
- (c) Intellectual Property Agreement.

The employee must also be finger-printed by the Human Resources Division.

- (3) The Research Service will verify declared education, certification and/or any licenses.
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

**h. Volunteers involved with PVAMC IRB-approved human research projects**

**Exception: The volunteer is or will be credentialed through VetPro.**

(1) The Volunteer must complete and submit the following to the Research Service, as indicated on the checklist in Appendix G:

- (a) Scope of Work form that has been signed by the Supervisor/Principal Investigator;
- (b) Education Verification Form for each degree, certification, or license earned; and
- (c) Copy of Professional License (if required for interaction with patients in a supervised setting)

- (2) Volunteers that will be participating on a PVAMC IRB-approved research project for at least 60 calendar days must also have a WOC appointment. The Volunteer must complete and submit the following to the Research Service:
  - (a) OF 612 Form;
  - (b) Copy of Curriculum Vitae (if available) or resume; and
  - (c) Intellectual Property Agreement.The volunteer must also be finger printed by Human Resources Division.
- (3) The Research Service will verify declared education and/or certification(s).
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

**i. Education Verification**

- (1) Attendance, education, and/or degrees earned as declared by personnel on the Education Verification Form will be verified at the primary source. A reasonable effort will be made by the Research Service to identify and verify earlier degrees (e.g. bachelors or masters degrees) if only more advanced degrees were initially reported by an individual.
- (2) Personnel who have not completed education or received a degree from a higher source of education than high school shall have the Supervisor provide a written declaration that the individual is capable of performing the duties required of the position and declare that the individual has or will be trained appropriately.
- (3) Acceptable verification sources include:
  - (a) National Student Clearinghouse: [www.degreeverify.com](http://www.degreeverify.com);
  - (b) Credentials, Inc.: [www.degreechk.com](http://www.degreechk.com); and
  - (c) Direct communication (via fax, telephone, e-mail, transcript, website, etc.) with the education institution or the appropriate record retention warehouse.
- (4) Two attempts will be made to verify each education component identified on the Education Verification Form or VA application. If these two attempts are unsuccessful, a good faith effort has been made consistent with VA guidelines.
- (5) Written documentation of verification(s) should be received. If written documentation is or may not be obtained in a reasonable time frame, verbal verification is appropriate.
- (6) All attempts of education verification will be filed appropriately in the personnel's human subjects research credentialing file.

**j. License/Certification Verification**

- (1) Personnel that declare a professional license that is required for interaction with patients in a supervised setting will have the license and/or certification verified.
- (2) Acceptable verification sources include:
  - (a) State Board or licensure/certification websites and
  - (b) Direct communication (via fax, telephone, e-mail, website, etc.) with the licensing or certifying institution or the appropriate record retention warehouse.
- (3) Only those license(s) that are currently active will be verified. Only certifications that directly relate to human studies research and that are currently active or have been received in the year prior to involvement with human studies research at the PVAMC will be verified.
- (4) Verification of license(s) and certifications will be filed appropriately in the personnel's human subjects research credentialing file.

**k. Without Compensation (WOC) Appointments**

- (1) Individuals who are not PVAMC employees and are working on PVAMC IRB-approved research projects that exceed 60 days must have a WOC appointment.

**VA MEDICAL CENTER, PORTLAND, OREGON**  
**Human Research Protection Program: Policy & Procedure No. 10**

**Effective: 08/01/2005**

- (2) The WOC appointment may be through the Research Service or other service if more appropriate.
- (3) The Research Service will initiate and follow-up on the status of the WOC appointment for individuals requiring a WOC appointment through the Research Service.

**l. Background Investigations**

Individuals involved in human subjects research must have background investigations that are related to the risk level of their position. This is part of the normal VA hiring process. The Research Service will adhere to the Human Resources Division policies for background investigations, consistent with VA policy.

- (1) VA employees have a full background investigation.
- (2) All individuals with a WOC appointment must be fingerprinted. If the results of the fingerprinting are questionable, a full background investigation must be completed.

**m. Exclusionary Lists**

- (1) Individuals involved in human subjects research will be verified against the following exclusionary lists monthly:
  - (a) Department of Health & Human Services Office of the Inspector General, List of Excluded Individuals/Entities (LEIE) List:  
<http://www.oig.hhs.gov/fraud/exclusions/listofexcluded.html> and
  - (b) Food & Drug Administration Debarment List: [http://www.fda.gov/ora/compliance\\_ref/debar/](http://www.fda.gov/ora/compliance_ref/debar/).
- (2) In the event an individual appears on either exclusionary list, the AO/R&D and ACOS/R&D will be notified immediately. Appropriate action will be taken with consultation from Human Resources Division.

**n. Record Retention**

Human subjects research credentialing files will be maintained for six years after the termination date of the appointment.

- 5. REFERENCES:** Credentialing of Personnel Involved in Human Subjects Research Memorandum from the Deputy Under Secretary for Health Operations and Management  
VHA Handbook 0710, Personnel and National Information Security, October 30, 2000
- 6. CONCURRENCES:** Endorsed by the Research & Development Committee on 08/01/2005
- 7. RESCISSION:** HRPP: P&P No. 10, Endorsed by the Research & Development Committee on 01/26/2004 and 04/04/2005.
- 8. FOLLOW-UP RESPONSIBILITY:** ACOS, R&D Service

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