CREDENTIALING, VERFICIATION OF QUALIFICATIONS AND APPOINTMENTS FOR PERSONNEL IN RESEARCH & DEVELOPMENT SERVICE

SOP RES-002-RD

VA Portland Health Care System
Portland, OR 97219

Signatory Authority:
Associate Chief of Staff, Research and Development Service

Responsible Owner:
Administrative Director, Research and Development Service

Service Line(s):
Research and Development Service

Effective Date:
April 5, 2021

Recertification Date:
April 5, 2026

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) is to establish procedures on personnel involved in human, animal and laboratory research and a compliance system for the credentialing, verification of qualifications and appointments of such personnel. This SOP must be followed by Research and Development Service Staff Members who process changes in Research staff.

b. This SOP sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.01(1), Veterans Health Administration Research and Development Program dated January 24, 2019 (amended January 8, 2021); VHA Directive 1200.02(1), Research Business Operations dated March 10, 2017 (amended September 6, 2017); and VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research dated January 7, 2019 (amended January 8, 2021).

2. PROCEDURES

a. All research personnel must submit an Education Verification form to the Research Administration (RA) Office.

b. All research personnel who work on human, animal and/or laboratory research must complete a Scope of Work (SoW) form(s), signed by themselves and the principal investigator (PI) of the research project(s) in which they may be involved. For human research, the SoW form will be specific to each person for each approved protocol. For lab and/or animal research, the SoW form will be specific to each PI for whom an individual works. SoW forms must receive concurrence from the Associate Chief of Staff (ACOS)/R&D or designee before the individual begins work on the related research.

c. All research personnel involved with human research must be credentialed (except for personnel who only perform administrative work). If they are hired for their clinical expertise, they must be credentialed in the web-based Federal Credentialing

Program for Healthcare Providers (VetPro). If they were not hired for their clinical expertise, the information on their Education Verification form will be verified using primary verification sources (e.g. National Student Clearinghouse).

(1) Personnel who require VetPro credentialing include those hired in human research for their clinical expertise. For example, this includes a nurse who will perform nursing-level activities for a study, or a psychologist who will conduct psychological exams for the study, if that activity would normally require credentialing to be performed clinically.

(2) Exception to the requirement for VetPro: Residents, fellows and clinical trainees must be verified via a RCVL from the Medical Professional Service Office, or, in the case of trainees in Mental Health, a TQCVL from the Education Office. Any resident, fellow or trainee from OHSU, who will not have a clinical rotation and will only work on VA research at VAPORHCS and therefore does not have an RCVL or TQCVL on file at VAPORHCS, and will be using their clinical expertise for the research project, must be credentialed in VetPro.

d. Research staff must obtain either a VA-paid or WOC appointment if they will:

(1) work on VAPORHCS property;

(2) interact with VAPORHCS research participants via telephone or in-person, except as listed in item e. below;

(3) collect and analyze individually identifiable laboratory specimens or data of participants in a VAPORHCS-approved study;

(4) perform laboratory tests on specimens, or work with identifiable data, of participants in a VAPORHCS-approved research study; or

(5) work in the RA Office [i.e. ACOS/R&D, Deputy ACOS/R&D, AO/R, R&DC Coordinator, IRB Analysts, IACUC Coordinator, Subcommittee on Research Safety Coordinator, Grants Administrators, Research Assurance Officer (RAO), R&D Service Staff].

e. Personnel involved in VAPORHCS human research projects who meet the following criteria are NOT required to have credentialing completed:

(1) members of the research team who are strictly administrative staff (e.g., receptionist or any individuals that may have contact with a patient for scheduling purposes only);

(2) members of the research team (e.g., biostatisticians or lab technicians) who do not come to the VAPORHCS and do not directly interact with VA research participants or see their identifiable specimens or data;

(3) non-affiliated volunteers who serve on an IRB or R&DC; and/or

(4) members of research-related groups, such as Data Safety Monitoring Boards (DSMBs), who are recruited from non-VA institutions.

f. Individuals who do not meet the criteria above in item e. and are applying for either VA-paid or research WOC appointment must submit the following to the RA Office:

(1) the applicable appointment checklist; and

(2) all applicable forms as prompted on the checklist. NOTE: The checklist and forms are available on the R&D Service website at: https://www.va.gov/portlandresearch/piservices/hiring/appointmentrequirements.asp

g. A RA Office staff member (designated by the AO/R&D) will:

(1) Review SoW forms, follow-up concerning any questions, and obtain ACOS/R&D concurrence for each SoW.

(2) For those who are hired for their clinical expertise on human research, assure VetPro has been completed, and, if necessary, submit a request for VetPro credentialing to Medical Professional Services or Nursing Professional Services.

(3) For medical residents, fellows and trainees, assure that a current RCVL or TQCVL is on file.

(4) Complete a primary source verification of education for those individuals not credentialed through Medical Professional Services or Nursing Professional Services who will be working on human subjects research.

(5) Maintain credentialing files for all individuals working on VAPORHCS-approved research.

(6) Check the following:

(a) FDA Debarment List and FDA Disqualified/Restricted/Assurance List for Clinical Investigators on the FDA website.

(b) Public Health Service Administrative Actions Listing.

(c) System for Award Management (SAM).

(d) Research Misconduct List information on ORO's Web site.

(e) Research Personnel Database for expired VetPro appointments and residency/fellowships.

h. **Record Retention.** Credentialing files will be maintained in accordance with current records control schedule requirements.

3. ASSIGNMENT OF RESPONSIBILITIES

a. **The Associate or Deputy Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for:

(1) Completing their own credentialing requirements, as defined by national and/or local policy.

(2) Completing their own SoW form for any research on which they work, as required per national and/or local policy.

(3) Developing and managing credentialing policies and procedures for personnel involved in human, animal and laboratory research.

(4) Ensuring that all VAPORHCS research personnel involved in human research have completed the appropriate credentialing requirements, consistent with VA policy.

(5) Reviewing and providing concurrence for each appropriately completed SoW form.

b. **The Administrative Officer for Research & Development (AO/R&D)** is responsible for:

(1) Completing their own credentialing requirements, as defined by national and/or local policy.

(2) Completing the SoW form for any research on which they work, as required per national and/or local policy.

(3) Overseeing the RA Office staff involved with the process of credentialing personnel involved in human research.

(4) Working with Human Resources to ensure without compensation (WOC) appointments are completed, when appropriate.

(5) Overseeing the RA Office staff involved with initially reviewing SoW forms.

(6) Maintaining SoW of Work files for all research personnel.

c. A RA Office Staff Member(s) (designated by AO/R&D) is responsible for:

(1) Determining which individuals require credentialing in VetPro.

(2) Requesting VetPro credentialing, for applicable individuals, through Medical Professional Service, Nursing Professional Service or Human Resources, as appropriate, and documenting the VetPro appointment and expiration date in the appropriate research database.

(3) Assuring a RCVL or TQCVL, if applicable, is on file and recording the expiration date in the appropriate research database.

(4) Conducting primary source verification of education for individuals not credentialed in VetPro who work on human subjects research.

(5) Monitoring personnel compliance with the credentialing requirements.

(6) Reviewing and routing all SoW forms for concurrence by the ACOS/R&D and subcommittee or committee approval, as applicable, per this policy.

(7) Informing the AO/R&D and ACOS/R&D of areas of noncompliance with credentialing requirements.

(8) Maintaining the SoW and Credentialing section of the appropriate research database.

(9) Assuring all research appointees in human research are not the subject of regulatory action and have completed all credentialing requirements.

(10) Maintaining documentation of SoW and Education Verification for all personnel working in research

d. All Research staff are responsible for completing the Education Verification form, any applicable credentialing requirements and the applicable SoW form(s).

e. PIs are responsible for reviewing and signing the SoW forms and, for human research, submitting completed SoW forms when requesting to initially add an individual to their study.

4. DEFINITIONS

a. **Credentialing**. A systematic process of screening and evaluating an individual's qualifications and other credentials, including licensure, education, training, and experience and current competence and health status.

b. **Federal Credentialing Program for Healthcare Providers (VetPro)**. A web-based data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate, complete credentials file.

c. **Research Personnel**. Includes, but is not limited to, VAPORHCS-paid employees (Title 5, Title 38 and Title 38 Hybrid), Portland VA Research Foundation (PVARF) employees, Oregon Health & Science University (OHSU) employees, other without compensation (WOC) appointments, residents, trainees, fellows, and fee-basis, consulting and attending providers.

d. **Resident Credentials Verification Letter (RCVL)**. A document certifying that all documents needed, including credentials, for appointment of an individual into a program are in order. A new RCVL is required for each academic year appointed, before approval of appointment is granted by the Health Care System Director.

e. **Scope of Work (SoW)**. A written document that defines the parameters and functions of an employee's duties and responsibilities. These duties and responsibilities must be consistent with the occupational category under which they:

(1) are hired (appointment by Human Resources to the position); allowed by the license, registration, or certification that they hold; consistent with their qualifications (education and training); and agreed upon by the person's immediate supervisor and the ACOS/R&D.

f. **Trainee Qualifications and Credentials Verification Letter (TQCVL)**. A document that contains student information. It is completed by an affiliate medical school that documents that the student is in good standing and has a current Basic Life Support (BLS) card and the required immunizations.

g. **Without Compensation (WOC) appointment**. An appointment to work at the VAPORHCS where the individual is not compensated by the VAPORHCS for their services.

5. REFERENCES

a. VAPORHCS Research & Development, Research Appointment Requirements webpage:
https://www.va.gov/portlandresearch/piservices/hiring/appointmentrequirements.asp

b. VHA Directive 1200.01(1) Veterans Health Administration Research and Development Program, January 24, 2019 (amended January 8, 2021),
http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

c. VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017 (amended September 6, 2017),
http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

d. VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019 (amended March 3, 2020January 8, 2021,
http://vaww.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

6. REVIEW

This SOP must be reviewed, at a minimum, at recertification, when there are changes to the governing document, and any regulatory requirement for more frequent review.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of April 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

DAVID M COHEN 386526
Digitally signed by DAVID M COHEN 386526
Date: 2021.04.08 12:40:04 -07'00'
David M. Cohen, MD
Associate Chief of Staff/R&D
Service Date Approved: 4/8/2021

Merritt H Raitt 388523
Digitally signed by Merritt H Raitt 388523
Date: 2021.04.08 15:05:10 -07'00'
Merritt Raitt, MD
R&D Committee Chairperson
Date Approved: 4/8/2021

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: SOPs are available at:
https://www.a.gov/portlandresearch/R&D_Forms.asp