

RESEARCH CREDENTIALING

SOP SD-004

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line:
Research Service

Signatory Authority:
Neal Peachey, Ph.D. ACOS/Research

Effective Date:
July 7, 2022

Responsible Owner:
Program Specialist Policy and
Education

Recertification Date:
July 7, 2027

1. PURPOSE AND AUTHORITY

a. To establish procedures pertaining to the training and credentialing of individuals involved in VA approved research at the VA Northeast Ohio Healthcare System (VANEOHS).

b. It is Veteran Health Administration (VHA) policy that all employees involved in research, must be appropriately trained, and credentialed and privileged (if applicable). All staff engaged in research are required to complete a specific credentialing process tailored to their individual employment status and research duties.

2. PROCEDURES

a. All individuals involved in VA research must have appropriate background investigations, credentialing completed, and a signed Human Resources (HR) Appointment Letter (if applicable) on file prior to hire and initiation of research duties. This includes, but is not limited to, background checks and verification of all research appointee degree(s), certification(s) and licensure(s), when applicable. This applies regardless of pay status, appointment type, or length of time in the VA facility, and includes research staff with a Without Compensation (WOC) appointment and those in volunteer status. This process includes the WOC appointment process.

b. All Licensed Independent Practitioners (LIPs), who perform independent clinical activities as part of their research activities, or who by the nature of their position have the potential to assume patient-care related duties and claim licensure, certification, or registration as applicable to their position within VHA are required to be credentialed by VetPro and the standard credentialing and privileging process.

c. For all other staff engaged in research that are not credentialed through VetPro, a paper credentialing process has been established, within the research office. This process includes completion of a Research Scope of Practice.

Note: Residents and Fellows are credentialed and privileged by the Affiliate and allowed to conduct clinical activities at the VA under provisions of the Resident

Credentials Verification Letter (RCLV) which is maintained within the Office of Education. These physicians are not LIPs and require a Research Scope of Practice.

d. Individuals who are employed by and credentialed through another VA do not need to be re-credentialed at the VANEOSH. They must provide a memo from their home institution research office confirming all research training and credentialing requirements are up to date. The memo must include the expiration date of both the Human Studies Research training and Scope of Practice. The memo must be updated annually or when the training and Scope of Practice have been renewed.

Note: The Research Credentialing Program resides within the Research Service Offices and involves collaboration with the Research & Development (R&D) Committee, the local Offices of Human Resource Management Services (HRMS), the Medical Staff Office, and Police Services.

e. The PI or designee will provide the Research Credentialing Coordinator (RCC) the employment status of the study staff. The RCC will notify the study staff of the required credentialing requirements and enter the employee into the Research tracking system. An electronic file, as detailed below, will be maintained for each study member.

(1) All study staff participating in research:

- New Employee Form
- Dated copy of CV or Resume
- Research Scope of Practice Form
- Research Service Safety Training required for:
 - Individuals who have access to VA secured areas
 - Individuals listed on a non-exempt research protocol safety survey
 - Individuals who are VA research employees or VA research WOC appointees

(2) Employees participating in Human Subject research:

- Forms listed under 2e(1)
- Human Subject Protection (HSP) Training

(3) Employees participating in Animal research or requiring access to secured lab areas:

- Forms listed under 2e(1)
- Animal Allergy/Occupational Health Questionnaire (if working with animals)
- IACUC Training (if working with animals)
- Research Service Safety Training

(4) VA Employees from other VAs participating in VANEOSH research:

- Forms listed under 2e(1)
- HSP Training (if applicable)
- IACUC Training (if applicable)

NOTE: Memo or copies of credentialing documents from home institution may be submitted.

(5) Research and Development Committee Member

- Forms listed under 2e(1) except the Scope of Practice
- HSP Training

(6) Institutional Review Board Committee Member

- Forms listed under 2e(1) except the Scope of Practice
- HSP Training

(7) Institutional animal Care and Use Committee Member (IACUC)

- Forms listed under 2e(1) except the Scope of Practice
- IACUC Training

(8) Subcommittee on Research Safety

- Forms listed under 2e(1) except the Scope of Practice
- Research Service Safety Service Training

3. ASSIGNMENT OF RESPONSIBILITIES

a. Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for ensuring that:

(1) All research staff are appropriately trained, credentialed, and privileged (if applicable).

(2) Specific procedures are developed to ensure compliance with the requirements of this SOP.

b. The R&D Committee is responsible for:

(1) Assuring that credentialing and training requirements are complete for all research staff.

(2) Approving all investigators and staff to work on VA-approved research by approval of subcommittee actions and approvals.

c. Principal investigators involved in research are responsible for ensuring that all employees under their supervision, working on approved VA research:

(1) Have completed required training.

(2) Have approved research scope of practice statements or clinical privileges that are consistent with the employees' qualifications and that employees are working within their Scope of Practice or Functional Statement.

(3) Review research scope of practice statements. If an employee is on more than one study, only one scope of practice is needed that encompasses all of the duties that the employee is authorized to perform.

d. Medical Research Service Credentialing Coordinator (RCC) is responsible for providing management of the documentation, processing and credentialing of research staff including:

(1) Initiation of Research appointments.

(2) Maintaining electronic files for all appointees.

(3) Review research scope of practice statements. If an employee is on more than one study, only one scope of practice is needed that encompasses all of the duties that the employee is authorized to perform.

4. DEFINITIONS

DEFINITION. The following definitions apply throughout this policy:

a. Clinical Privileging: Clinical Privileging is defined as the process by which a practitioner, licensed for independent practice (i.e., without supervision, direction, required sponsor, preceptor, mandatory collaboration, etc.), is permitted by law and the facility to practice independently to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure. Clinical privileges must be facility-specific and provider-specific (see VHA Handbook 1100.19).

b. Credentialing. Credentialing is the systematic process of screening and evaluating qualifications and other credentials, including licensure, registration, certification, required education, relevant training and experience, and current competence.

c. The term "licensure" refers to the official or legal permission to practice an occupation, as evidenced by documentation issued by a State, Territory, Commonwealth, or the District of Columbia (hereafter referred to as "State") in the form

of a license, registration, or certification. (See VHA Handbook 1100.19 and VHA Directive 1100.20).

d. Registration or Certification. Registration and certification are terms that refer to the official attestation by a professional organization that one has fulfilled the requirements or met a standard or skill to practice the profession (see VHA Handbook 1100.19).

e. VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated.

f. VetPro. VetPro is an Internet-enabled data bank for the credentialing of VHA health care providers that facilitates completion of a uniform, accurate, and complete credentials file (see VHA Handbook 1100.19).

g. Research Staff include Principal Investigators, Responsible Investigators, Co-Principal Investigators, Co-Investigators, Study Coordinators, and those who interact with patients in person and/or on the telephone and those who collect and analyze individually identifiable data. This applies regardless of pay status, appointment type, and length of time in the VA facility and includes research staff with a WOC appointment. This also includes all R&D Committee and Subcommittee members excluding community volunteers (Institutional Review Board (IRB) Researchers, R&D Committee, Institutional Animal Care and Use Committee (IACUC), Lab, Animal Researchers, and Subcommittee on Research Safety), and Research Administrative Staff, exclusive of secretarial support.

h. Research Scope of Practice: A Research Scope of Practice statement is a written document that defines the parameters and functions of an employee's research duties and responsibilities. These duties and responsibilities must be consistent with the occupational category under which they are hired (appointed by HRM to the position) allowed by license, registration, or certification they hold, consistent with their qualifications (education and training) and be agreed upon by the person's immediate supervisor and the Associate Chief of Staff for Research and Development (ACOS/R&D). When the employee is working on more than one research study, only one approved Scope of Practice is required if it covers all research duties performed.

i. Employees Exempt from this credentialing requirement:

1) Co-investigators who may collaborate with VA researchers but who do not work at the VA, do not perform VA research, and do not enroll VA patients.

2) Community representatives on R&D committees and subcommittees including IRB and IACUC who do not have direct contact with patients or research subjects and who only see de-identified information.

- 3) Biostatisticians at an affiliate or outside institution working with de-identified research data.
- 4) Lab technicians at an external IRB-approved laboratory who may process VA research specimens.
- 5) VA Clinical personnel who periodically perform tests on research patients as part of their routine jobs.
- 6) Members of groups such as Data Safety Monitoring Boards (DSMB) who are recruited from non-VA institutions and work external to the VA.
- 7) Research Study Sponsor Monitors who periodically come to the VA to audit research studies on the behalf of the sponsoring agencies. See VANEOHS Standard Operating Procedure HSP-018 “Study Monitoring Visits – Process for Access to Information and Reporting of Site Visit Results” for more information.

5. REFERENCES

VHA Directive 1200.01, VHA Handbook 1100.19, VHA Directive 1100.20

6. REVIEW

At recertification or when there are changes to the governing documents.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of July 7,2025. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

Neal S. Peachey, Ph.D.
Associate Chief of Staff/Research

Date Approved: July 21, 2022

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

DISTRIBUTION: This SOP will be posted on the VA Research website:
<https://www.clevelandvaresearch.org/>