



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

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Version 3.6

**SOP: Credentialing of  
Individuals Involved in Human  
Subjects  
Research At the Jesse Brown  
VA Medical Center**

**PURPOSE**

To describe the process and procedures regarding the credentialing of research personnel at the Jesse Brown VA Medical Center

**POLICY**

To require that all employees involved in human subjects research (Title 38, Title 5) possess adequate credentials and privileges to perform the activities assigned to them in the research study.

**BACKGROUND**

The Department of Veterans Affairs (VA) is guided by ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies, all Veterans Health Administration (VHA) personnel involved in human subject's research must demonstrate and maintain the appropriate education, training, and experience to provide the highest level of protection to human subjects.

Credentialing requirement applies to all research staff including those that are compensated by the VA, those that are appointed as Without Compensation (WOC), and those appointed by the Intergovernmental Personnel Act Mobility Program (IPA). The staff may be full time, part time, or fee basis.

## **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. Each member of the research staff must be appropriately credentialed, except individuals providing secretarial support who should undergo the Human Resource Management (HRM) process for administrative personnel.

## **Privileges**

For the purposes of this SOP, the terms "privileging" and "clinical privileging" are the same and are 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: (a) to practice independently; and (b) 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.

If the local facility where the research is to be performed requires privileging to perform a given duty (e.g., a procedure) in the clinical setting, the individual must be privileged at that facility to perform the duty before the individual can perform that duty in the research setting.

If the local VA facility requires privileging to perform a given procedure, it is not sufficient for only the supervisor of the person performing the research procedure to be privileged for that procedure. The person actually performing the research procedure must be privileged for the procedure.

## **Unlicensed staff**

All staff that by virtue of their education and training is eligible to obtain licensure, registration, or certification is required to be credentialed through Vetpro even if they do not hold an active license, registration, or certification at the time they are appointed. Unlicensed nurses, physicians, pharmacists, clinical psychologists, and others requiring licenses, registration, or certifications for clinical practice cannot be hired into those occupations unless they obtain an active license, registration, or certification for the occupation and qualify under VA qualification standards. If they do not obtain the license, registration, or certification they must be hired under some other occupational category for which they qualify. If this other occupational category allows a scope of practice to perform procedures AND there is no requirement for licensure or certification, then with a duly exercised scope of practice after the appropriate credentialing could be processed. *Note: See VHA Directive 2006-067 for a list of all effected occupations.*

## **VetPro: Staff that must be credentialed in VetPro**

- All health care professionals who claim licensure, certification or registration as applicable to their position within VHA.

- All research staff that holds a degree that may make them eligible for licensure, registration, or certification. Such persons would include but is not limited to: nurses, physicians, Foreign Medical Graduates, Clinical Psychologists, and pharmacists that do not have a current active license. Note: See VHA Directive 2006-067 for a more complete list.
- All research staff including research administrative personnel, who by the nature of their position have the potential to assume patient care-related duties, or oversee the quality or safety of the patient care delivered, e.g. Research Assistants, Project Officers, etc.

### **Scope of Practice or Functional Statement**

A Scope of Practice or Functional Statement outlines all the duties of employees. These duties must: 1) be consistent with the occupational category under which they are hired, 2) allowed by the license, registration, or certification they hold, 3) consistent with their qualifications (education & training), and 4) be agreed upon by the person's immediate supervisor and the ACOS. *Note: When working on specific research protocols, the Principal Investigator for each protocol must also agree.*

- If research personnel are involved in more than one study, the research scope of practice statement or functional statement may be written to cover multiple studies (i.e., personnel do not need a research scope of practice statement for each protocol).
- If an employee's clinical privileges, clinical scope of practice statement, or clinical functional statement includes all of the duties necessary for a specific research study (e.g., taking a medical history, drawing blood, performing a muscle biopsy, ordering and interpreting laboratory tests), a separate research scope of practice statement or functional statement does not need to be developed. However, if there are additional duties, these need to be included in the research scope of practice statement along with a copy of the clinical privileges, clinical scope of practice statement, or clinical functional statement.

### **Clinical Privileges**

If the person's license allows for independent practice and the facility chooses to allow independent practice, privileges must be granted in accordance with VHA Handbook 1100.19 and the facility's Medical Staff Bylaws, Rules and Regulation prior to performing the interventions covered under the privileges they have been granted.

### **Points to consider**

Individuals must not practice beyond the occupation they are hired/appointed into and their Scope of Practice or Functional Statement. Principal Investigators are responsible for the overall conduct of their research protocols including ensuring that all research staff for the protocol are working within their Scope of Work or Functional Statement.

The appropriate background check as defined in VA Directive and Handbook 0710 must also be completed. *Note: For those employees working with Select Agents or Toxins, additional background investigations must be completed. See VHA Handbook 1200.06 for more information.*

Trainees from our academic affiliates must have a Resident/Trainee Credentials Verification Letter (RCVL) prior to any interactions with research subjects. VHA Handbook 1400.1 contains further information regarding residents and trainees.

## **DEFINITIONS**

- A. Background Investigations: This term refers to the investigation of the applicant's past history to a degree that is commensurate with the risk level assigned to the employee's Functional of Research Duties and Responsibilities.
- B. Belmont Report: This term refers to the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979.
- C. Common Rule: This term refers to a common set of regulations governing human subject research which are codified at Title 38 Code of Federal Regulations (CFR) Part 16.
- D. Credentialing: Credentialing is the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials that include education, licensure, relevant training, experience, and competence.

## **RESPONSIBILITIES**

### **Human Resource Management (HRM)**

HRM has the primary responsibility for verifications of candidates qualifications including education, relevant training and experience, and current competence to hold the position. HRM is also responsible for checking US citizenship or visa status.

### **ACOS/R&D and/or AO/R&D**

Either the ACOS/R&D and/or the AO/R&D must ensure that all research staff:

- Have been credentialed prior to appointment. If not, they must be credentialed ASAP. *Note: Credentialing for those who are covered by Directive 2006-067 and VHA Handbook 1100.19 must be credentialed through VetPro. Staff that hold a degree that may make them eligible for licensure, registration, or certification related to in health care must also be credentialed through VetPro.*

- Have a Scope of Practice or Functional Statement that is consistent with their education, licensure, or certification, and
- Have been granted the appropriate privileges, if applicable under the facility's Bylaws,

In addition, the following must be done:

- Annually ascertain compliance with these requirements.
- Maintain records that will adequately show these responsibilities have been fulfilled.

## **PROCEDURES**

- A. Credentialing and validation of qualifications applies to all members of the research team (except administrative staff) and includes the following:
- (1) Research staffs who interact with patients via telephone
  - (2) Research staffs that collect and analyze laboratory specimens or data.
  - (3) Research staff that perform laboratory tests and work with data.
  - (4) Research staff with or Without Compensation (WOC) appointment.
- B. Credentialing and validation of qualifications is not required for the following:
- (1) Research staff that are based at an affiliate or other outside institution and who will not access VA patients/data or access VA space for research activities.
  - (2) Outside biostatisticians.
  - (3) Outside laboratory technicians.
  - (4) Community volunteers who represent the VA on an Institutional Review Board or the Research & Development (R&D) Committee.
  - (5) Subjects in data safety monitoring boards who are recruited from non-VA institutions.
  - (6) Clinical personnel who periodically perform tests on research patients as part of their routine duties.
- C. Individuals involved in human subject research will receive appropriate training in the ethical principals and good clinical practices for human subjects research on an annual basis.
- D. All employees involved in human subject research will have appropriate background investigations; Human Resources personnel will oversee the background investigation procedures.
- E. All employees involved in human subject research will be credentialed and have relevant qualifications appropriately validated, including licensure and educational verifications from primary sources.
- F. All employees involved in human subject research will have approved clinical

privileges or functional statements of research duties and responsibilities that are consistent with their assigned activities. Specifically, Licensed Independent Practitioners (LIPs) will be credentialed through the VetPro procedures within the Chief of Staff's Office. Non-LIP research staff will be credentialed through the Research Office. Professional licenses will be confirmed annually.

- G. Employees involved in human research will undergo employment screening via the List of Excluded Individuals and Entities (maintained by the Department of Health and Human Services) and the Department List (maintained by the Food and Drug Administration).
- H. Re-credentialing will be required every two years.
- I. Employees involved in human subject research are responsible for knowing and adhering to the scope of practice or clinical privileges that have been approved for them.
- J. Employees involved in human subject research are responsible for knowing and adhering to the applicable statutes, regulations, and policies related to the conduct of human subjects research.
- K. Employees involved in human subject research are responsible for completing required training in the ethical principles and acceptable human research practices on an annual basis.
- L. Employees involved in human subject research are responsible for engaging only in human subjects' research activities that have been approved, as required by VA regulations and policies, by the R&D Committee.

## **REFERENCES**

Title 21 Code of Federal Regulations (CFR) Parts 50, 56, 312, and 812  
Title 38 USC Section 7304  
Title 38, CFR Part 16  
VA Handbook 5005, Staffing, Part II, Chapter 3, Section B  
VHA Directive 1200.05 "Requirements for the Protection of Human Subjects Research"  
VHA Directive 2006-067 December 22, 2006 "Credentialing of Health Care Professionals"  
VHA Handbook 1100.19 March 6, 2001 "Credentialing and Privileging"  
VHA Handbook 1400.1 July 27, 2005 "Resident Supervisions"  
VA handbook and Directive 0710, September 10, 2004 "Personnel Suitability and Security"  
VA Handbook 5005 April 15, 2002 "Staffing"

**REVISION LOG:**

**SOP: Credentialing of Individuals Involved in Human Subjects Research at the Jesse Brown VA Medical Center**

<b>Version (#, date)</b>	<b>Replaces (#, date)</b>	<b>Summary of changes</b>
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