

Department of Veterans Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, MO 65201

HPM 589A4-342
March 28, 2011
Issued by: Research

CREDENTIALING AND PRIVILEGING OF RESEARCH STAFF

1. PURPOSE: To describe the policy and procedures for approval of the designated roles and responsibilities of research personnel at the Harry S. Truman Memorial Veterans' Hospital (Truman VA). This component of the Truman VA Research Program is designed to ensure that research personnel are qualified to conduct the research.

2. POLICY:

a. All individuals involved in research at the Truman VA must receive approval for their participation through the Research Office. One of the requirements for approval is having an approved Functional Statement of Research Duties & Responsibilities.

b. Personnel may have only the roles and responsibilities, as defined by their approved Functional Statement of Research Duties & Responsibilities, that are appropriate to their level of training, specific license, and/or clinical privileges. Licensed research personnel may not perform or be trained to perform procedures outside of those allowed under their respective license and clinical privileges. If a licensed clinician wishes to perform a clinical procedure for research purposes outside the scope of their current clinical privileges, the change must be approved through the Chief of Staff's Office. Unlicensed research personnel may not be trained to do procedures that require a medical license.

c. Non-licensed research personnel, including individuals who have an MD, DO, PhD, BSN, or MSN degree, without licensure (excluding those in a Truman VA approved training program), are not allowed to perform duties that would constitute the practice of medicine, including physical examination of subjects; ordering medications or investigational agents; altering or adjusting the dose of medications or investigational agents; evaluating acute medical problems, including adverse events; ordering, administering, or modifying intravenous solutions or medications; and any procedures that, according to the Truman VA bylaws, would require consent of the patient in a standard (non-research) patient care setting.

d. Research personnel may not participate in a research protocol until all requirements of this policy are met, including an approved Functional Statement of Research Duties & Responsibilities.

e. Unlicensed research personnel working as research coordinators or research fellows may obtain informed consent if competency verification has occurred on the Research Functional Statement of Research Duties & Responsibilities form and the Principal Investigator has delegated informed consent authority to that individual.

3. 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 subjects research must demonstrate and maintain the appropriate education, training, and experience to provide the highest level of protection to human subjects.

4. DEFINITIONS:

a. Credentialing. Credentialing is the formal, systematic process of verifying, screening and evaluating qualifications and other credentials that include required education, licensure, relevant training and experience, and current competence.

b. 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 an individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure. Clinical privileges must be provider specific and facility specific.

c. Licensure. Licensure refers to the official or legal permission to practice in an occupation, as evidenced by documentation issued by a State, Territory, Commonwealth, or the District of Columbia in the form of a license or registration.

d. Registration or Certification. Registration or certification 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.

e. Authenticated Copy. Authenticated copy means that each and every page of the document in question is a true copy of the original document and each page is stamped "authenticated copy of original," dated and signed by the person doing the authentication.

f. Primary Source Verification. Primary source verification involves receipt of documentation from the original source of a specific credential that verifies the accuracy of a qualification reported by an individual health care practitioner. This can be documented in the form of a letter, telephone contact, secure electronic communication with the original source, or when required by VA policy, it may be a transcript received directly from the issuing institution.

g. Background Investigation. 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 Statement of Research Duties and Responsibilities.

h. VetPro. VetPro is an internet enabled data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate, complete credentials file.

i. Current. Current applies to the timeliness of the verification and use for the credentialing process. No credential is current if verification is performed prior to submission of a complete application by the individual, including submission of VetPro. At

the time of initial appointment, all credentials must be current within 180 days of submission of a complete application.

j. Licensed Independent Practitioner (LIP). LIP refers to any individual permitted by law and the Truman VA to provide patient care services independently (i.e., without supervision or direction), within the scope of the individual's license and in accordance with individually granted clinical privileges. Only practitioners who are licensed and permitted by law and the facility to practice independently may be granted clinical privileges.

k. Research Staff Functional Statement of Research Duties & Responsibilities. This statement outlines the duties of employees involved in research that are authorized by the Principal Investigator. A Functional Statement of Research Duties & Responsibilities outlines the duties of a research employee as granted by the Principal Investigator. A Functional Statement of Research Duties & Responsibilities statement needs to be developed for each employee by each Principal Investigator for whom they work, not each protocol. Research staff involved in multiple studies should have one functional statement that encompasses all of the routine duties that they are authorized to perform for each Principal Investigator for whom they work. The Functional Statement of Research Duties and Responsibilities is granted and signed by the Principal Investigator(s) and reviewed and approved by the Associate Chief of Staff for Research and Development (ACOS/R&D).

l. Principal Investigator Functional Statement of Research Duties & Responsibilities. An individual functioning as a Principal Investigator must have a Functional Statement of Research Duties and Responsibilities if (a) that individual is not otherwise privileged by the facility and (b) they have a degree that may lead to licensure (e.g., MD, DO, RN, etc.).

m. Validation of Credentials. The validation of credentials refers to the verification of the degree and license of employees, appointed under Title 5 United States Code (U.S.C.), to positions that have positive education and/or licensure or registration requirements. All credentials are to be validated through primary source verification, whenever feasible.

n. 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.

o. Common Rule. This term refers to a common set of regulations governing human subjects research which are codified at Title 38 Code of Federal Regulations (CFR) Part 16.

5. RESPONSIBILITIES:

a. The Chief of Staff is responsible for:

(1) Compliance with the requirements for complete credentialing prior to appointment, and the continued maintenance of accurate, complete, and timely credentials of all individuals who claim licensure, certification, or registration.

(2) Ensuring all employees involved in research have had appropriate background investigations, have been credentialed or had their qualifications validated, and that licenses of individuals in positions requiring a license are verified for currency.

(3) Recommending or taking disciplinary action against Truman VA employees or appointees who fail to comply with the provisions of this Hospital Policy Memoranda (HPM).

b. Principal Investigators are responsible for ensuring:

(1) All research has been approved by the appropriate subcommittees and the R&D Committee.

(2) All employees under their supervision involved in research have approved Functional Statements of Research Duties and Responsibilities that are consistent with the employees' qualifications.

c. The ACOS/R&D is responsible for ensuring:

(1) All research staff have been credentialed prior to appointment.

(2) All research staff have a Functional Statement of Research Duties & Responsibilities that is consistent with their education, licensure, or certification.

(3) All research staff have been granted the appropriate clinical privileges (if applicable).

6. PROCEDURES:

a. Principal Investigators must complete and submit the Functional Statement of Research Duties & Responsibilities to the Research Office when an individual is first added to their research protocol(s), whenever the duties of the employee must be modified, and when notified that the two-year review is required. A revised Functional Statement of Research Duties & Responsibilities should be submitted if modifications are needed to cover duties on a new protocol.

b. The Associate Chief of Staff for Research and Development (ACOS/R&D) will review the Functional Statement of Research Duties & Responsibilities and approve if the requested roles and responsibilities are appropriate.

c. The Research Office will provide the employee with a copy of the approved Functional Statement of Research Duties & Responsibilities or notification of disapproval if the Functional Statement could not be approved as submitted. The new/revised Functional Statement will be entered into the employee file and tracked for two-year review.

d. All research staff that hold a degree that may make them eligible for licensure, registration, or certification but are not licensed must also be credentialed through VetPro (e.g., unlicensed physicians, clinical psychologists, nurses, etc.). The credentialing process must be completed prior to initial appointment. These individuals must also complete a Functional Statement of Research Duties and Responsibilities even if they are functioning as a Principal Investigator on a protocol.

e. Credentialing and validation of qualifications applies to all members of the research team including administrative personnel, who by the nature of their position have the potential to assume patient care-related duties, or oversee the quality of safety of the patient care delivered, and may include the following:

- (1) Research staff who interact with patients via telephone.
- (2) Research staff who collect and analyze laboratory specimens or data.
- (3) Research staff who perform laboratory tests and work with data.
- (4) Research staff with a Without Compensation (WOC) appointment.

f. Credentialing and validation of qualifications are not required for the following:

(1) Research staff who 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) Participants in data safety monitoring boards who are recruited from non-VA institutions.

(5) Clinical personnel who periodically perform tests on research patients as part of their routine duties.

g. Individuals involved in human subjects research will receive appropriate training in the ethical principals and good clinical practices for human subjects research on an biennial basis.

h. All employees involved in human subjects research will have appropriate background investigations; Human Resources personnel will oversee the background investigation procedures.

i. All employees involved in human subjects research will be credentialed and have relevant qualifications appropriately validated, including licensure and educational verifications from primary sources.

j. All research staff involved in human subjects research will have approved clinical privileges and/or functional statements of research duties and responsibilities that are consistent with their assigned activities.

k. Licensed Independent Practitioners (LIPs) or individuals who are license-eligible will be credentialed through VetPro.

l. Employees involved in research will undergo employment screening via the List of Excluded Individuals and Entities (maintained by the Department of Health and Human Services) and the Debarment List (maintained by the Food and Drug Administration).

m. Re-credentialing will be required every two years.

n. Employees involved in human subjects research are responsible for knowing and adhering to their approved research scope of practice and/or clinical privileges.

o. Employees involved in research are responsible for knowing and adhering to the applicable statutes, regulations, and policies related to the conduct of human subjects research.

p. Employees involved in human subjects research are responsible for engaging only in human subjects research activities that have been approved, as required by VA regulations and policies, by applicable subcommittees and the R&D Committee.

7. RESCISSION: HPM 589A4-342 dated June 22, 2009

8. 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

VA Handbook 0710

VA Handbook 1100.19

VHA Directive 1200.05 "Requirements for the Protection of Human Subjects Research"

VHA Directive 2003-036 "Credentials and Training of Employees Involved in

Human Subjects Research"

VHA Directive 2006-067 "Credentialing of Health Care Professionals"

9. FOLLOW-UP RESPONSIBILITY: ACOS/R&D

APPROVED:

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Date: 3/28/11

Key Words:

Research
Credentialing
Functional Statement
VetPro
Licensure