RESEARCH STANDARD OPERATING PROCEDURES (SOP)

Verification of Education and Credentialing for Research Personnel

1. PURPOSE: The purpose of this Research Service SOP is to describe the policy and procedures for verification of education, credentialing, and research privileges for all personnel involved in research at the STVHCS.

2. POLICY: All personnel involved in human subject research must possess adequate credentials and training to ensure fulfillment of their obligation to the protection of human subjects and ethical conduct of research. The education, licensure, and training that are relevant to the research activities performed by the employee must be documented and verified.

3. ACTION: The granting or verification of research privileges requires the following actions:

   a. At the time a project is originally submitted, and when the project undergoes Continuing Review, the eligibility of each research personnel must be verified.

   b. Individuals exempt from eligibility verification requirements:

      (1) Individuals who are strictly administrative staff (e.g. receptionist, including any individual that may have contact with a patient for scheduling purposes only)

      (2) Individuals who are located at an affiliated or other institution and do not come to the VA or do not directly interact with VA research participants or their identifiable specimens or personal health information.

      (3) Outside volunteers who serve on committees, e.g. Data Safety Monitoring Board (DSMB)

      (4) Individuals who periodically perform tests on research subjects as part of their routine clinical jobs (x-ray, nuclear medicine, medical lab)

   c. Verification of VA appointment: All individuals involved in VA research must be either VA salaried, have a WOC appointment verified by receipt of a copy of the appointment letter, or be on an IPA paid for by a VA funded grant. For fellows, residents, and 3rd and 4th year medical students, a copy of their WOC appointment letter is obtained from the Education Office.

   d. Verification of educational degree(s):

      (1) The R&D Office will verify the educational degree(s) for all personnel requesting to be involved in human subject research prior to the approval of research privileges, unless verified through Vetpro HR (for example: nurses, respiratory therapists), Vetpro Medical Staff Office (for example physicians, physician assistants, PharmDs, clinical psychologists) or Residency programs. This verification is performed once prior to the initiation of research privileges.

      (2) Degrees will be verified using the following procedure:
(a) A signed Written Release of Information will be obtained from the employee who is requesting research privileges to enable the submission of a request for verification of degrees to the educational institution from which the employee received the degree.

(b) If on-line verification is available for the educational institution, an electronic request will be initiated.

(c) If the educational institution does not participate in centralized verifications, a form letter will be sent to the institution by mail. If no response is received, two additional follow-up requests will be sent (allowing 3 weeks before initiating follow-up). If no response to the third request is received, a notation will be placed in file stating that good faith attempt had been made. The employee will then be requested to provide college transcripts from the institution to be used as a secondary source.

(3) Upon verification, a hard copy of the verification will be maintained in the individuals’ personnel file and the verification information entered into the personnel database.

(4) The personnel database is to be queried each month to ensure that degree verifications are complete. If there is no degree this will be indicated as N/A. Personnel that are credentialed have had their degrees verified by either the Vetpro program, Nursing Board or Residency Program and therefore the Vetpro verification degree date will be entered for those individuals.

e. Verification of Human Research training within the last 3 years covering the required modules for the VA in CITI (Research Policy 18-29)

f. Verification of Current license/certification for licensed clinicians: Carried out by Vetpro HR, MSO or Residency program.

g. Credentials of research personnel that hold a degree that may make them eligible for licensure, registration, or certification (e.g. unlicensed foreign medical graduates) are not required to be credentialed in VetPro, VHA’s national electronic credentials databank.

h. Verification of absence from the DHHS exclusionary list: The DHHS exclusionary list (http://exclusions.oig.hhs.gov/) is checked by the Human Resources Office to ensure investigators or research personnel are not excluded from participation in federal health care programs.

j. Scope of Practice: An approved Research Scope of Practice or Functional Statement must be in place for all personnel involved in VA research. This will be verified by the R&D Office prior to granting research privileges, and again every year with continuing reviews of protocols. Each member of the research team must have a research scope of practice statement or functional statement that has been approved by the individual’s immediate supervisor and the ACOS for R&D and which defines the duties the person is allowed to perform for research purposes. A research scope of practice statement or functional statement must be developed for all research personnel (clinical and non-clinical) who are not privileged for all the duties the person is allowed to perform for research purposes. The research scope of practice statement or functional statement must be consistent with the occupational category under which the individual was hired, and it must not include any duties for which the individual is not qualified. Current scopes of practice for all non-privileged research personnel must be retained by the Research Office.

NOTE: A duty (e.g., a procedure) cannot be added to a scope of practice statement or functional statement, unless the individual meets all criteria to perform the duty in the clinical setting
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(e.g., the individual must be privileged for a procedure if privileging is required for that procedure in the local clinical setting).

k. 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 as long as the scope of practice statement covers all of the duties for all of the protocols).

l. 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.

m. Upon verification of the requirements for research privileges, a paper copy of the documentation of verification requirements will be maintained in the individual’s personnel file in the R&D Office and the verification information entered into the research personnel database.

n. License, Registration and Certification: The employee must have all required licenses, registrations, or certifications to perform a given procedure, intervention or other activity in the research setting and practice only within the scope allowed by such licenses, registrations, or certifications.

SUMMARY OF RESEARCH CREDENTIALLING AND PRIVILEGING

1. Licensed, privileged physicians who conduct research on human subjects do so under their approved clinical privileges. (Policy Memorandum 151-18-07)

2. Clinical privileges for a practicing physician who also conducts research are normally maintained through regular interactions with VA patients. It may be possible in selected instances for a physician whose only clinical practice is conducting clinical research, to use his/her documented interaction with human subjects as the basis for clinical review and re-privileging.

3. Non-licensed, and by inference non-privileged, physicians may not perform procedures as part of a research protocol that would constitute the practice of medicine. (VHA Directive 2009-054)

4. Licensed physicians who are not seeking clinical privileges at the STVHCS, must be credentialed through VetPro and reviewed but not privileged by the Professional Standards Board. (VHA Directive 2009-054)

5. All non-licensed physicians, and by inference licensed physicians who are not seeking clinical privileges at the STVHCS, must function under a research Scope of Practice approved by the ACOS/Research. (VHA Directive 2009-054 and Policy Memorandum 151-08-07)
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4. RESPONSIBILITY: Associate Chief of Staff for Research (151)

5. RESCISSION: March 2018

6. REFERENCES:
VHA Handbook 1100.19, Credentialing and Privileging
Requirements for Credentialing of All Research Staff, May 10, 2007
VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

6. RECERTIFICATION: March 2023

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