

RESEARCH SERVICE

March 30, 2008

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 participant 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. 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 or have a WOC appointment verified by receipt of a copy of the appointment letter. For fellows, residents, and 3rd and 4th year medical students, a copy of their 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, Nursing Board, or Residency programs. This verification is performed once prior to the initiation of research privileges.

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(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.

(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 no degree date will be entered for those individuals.

e. Verification of Annual Human Research training

f. Verification of Current license/certification for licensed clinicians: To verify the licensure of clinicians the following online sites will be searched.

Physicians	http://reg.tmb.state.tx.us/HomePgPub/Menu.asp
Nurses	http://www.bne.state.tx.us
Pharmacists	http://www.tsbp.state.tx.us/dbsearch
Dentists	http://www.tsbde.state.tx.us/dbsearch
Psychologists	http://www.tsbep.state.tx.us/profiles.html
Physical Therapist	http://ecptote.state.tx.us/license/verify_physical_therapist.php
Respiratory Therapist	http://legateway.dshs.state.tx.us/datamart/searchByName.do

Note: All other clinicians (to include clinicians holding licenses/certifications outside of the state of Texas) who are not listed in the above online sites, or whose verification does not provide an expiration date, must provide a hard copy of their current licensing/certification to the R&D Office.

g. Credential of research personnel that hold a degree that may make them eligible for licensure, registration, or certification (e.g. unlicensed foreign medical graduates) must 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 annually by the R&D Office to ensure and investigator or research personnel are not excluded from participation in federal health care programs.

i. Verification of absence from the FDA Debarment list: The FDA Debarment list is checked annually by the R&D Office to ensure and investigator or research employee is not barred from or subject to restrictions in participation in FDA regulated studies.

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- j. Scope of Practice: An approved Research Scope of Practice must be in place for all personnel involved in VA research. This will be verified by the R&D Office prior to granting of research privileges, and again every 2 years thereafter.
- k. 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

4. RESPONSIBILITY: Associate Chief of Staff for Research (151)

5. RESCISSION: None

6. RECERTIFICATION: March 2011

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PETER C. MELBY, M.D.
ACOS for Research and Development