

March 11, 2011

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Granting Research Privileges for Research Personnel Conducting
Human Subjects Research at the South Texas Veterans Healthcare System**

1. **PURPOSE.** This document outlines the current process of granting research privileges for research personnel at the South Texas Veterans Healthcare System (STVHCS) within the U.S. Department of Veterans Affairs (VA).
2. **BACKGROUND.**
 - a. The Research and Development (R&D) office is responsible for granting research privileges to research personnel that are involved in research that utilizes patients, resources, or facilities within the STVHCS. Granting research privileges is a multistep process that is facilitated by the R&D Office. Although the R&D Office is responsible for granting research privileges, the principal investigator (PI) for each VA research protocol is ultimately responsible for ensuring that ALL research personnel who perform research activities on a VA protocol have active research privileges. Research personnel cannot participate in a VA-approved research protocol until research privileges have been granted.
 - b. **Definitions**
 1. **Active Research Privileges.** Indicates that research privileges have been granted by the R&D Office AND all required documentation has been verified as complete and current by the WOC/Research Personnel Coordinator.
 2. **Exempt Personnel.** Research personnel not physically conducting research on VA property, only have access to de-identified data, not directly working with VA patients, and not conducting VA funded research activities.
 3. **Human Subjects Protocol Management Administrator.** This research administrator is responsible for processing all new protocol submissions and for conducting continuing reviews and evaluating and approving protocol modifications for all protocols involving human subjects.
 4. **Inactive Research Privileges.** Indicates that research privileges have been inactivated by the R&D Office either due to administrative action or because the investigator is no longer conducting VA-approved research.
 5. **Non-Physician Licensed Provider.** A non-physician healthcare provider that is currently licensed, certified, or registered to provide patient care or patient care

services (e.g. licensed/certified/registered nurses, pharmacists, physical therapists, respiratory therapists).

6. **Non-Physician Unlicensed Provider.** A non-physician healthcare provider that is ELIGIBLE to obtain licensure, certification, or registration according to their educational background, credentials, and experience, but is NOT currently licensed, certified, or registered to provide patient care or patient care services (e.g. unlicensed/uncertified/unregistered nurses, pharmacists, physical therapists, respiratory therapists).
7. **Pending Research Privileges.** Indicates that research privileges have NOT been granted by the R&D Office due to incomplete or expired documentation. ALL required documentation must be complete and current prior to activation of VA research privileges.
8. **Unlicensed Physician.** A U.S. or foreign physician that is ELIGIBLE to obtain licensure according to their educational background, credentials, and experience, but is NOT currently licensed to practice medicine in the U.S.
9. **Unlicensed Research Personnel.** All research personnel that are NOT ELIGIBLE to obtain licensure, certification, or registration according to their educational background, credentials, and experience to provide patient care or patient care services (e.g. BS biology, PhD pharmacology).
10. **WOC/Research Personnel Coordinator.** This research administrator is responsible for maintaining and verifying the validity of all personnel records required for granting of research privileges for research personnel conducting VA-approved research.

3. IDENTIFYING RESEARCH PERSONNEL. Identification of research personnel that require VA research privileging is accomplished by one of four ways:

- a. *New protocol submissions* – The Human Subjects Protocol Management Administrator is provided a VA research personnel list by the PI as part of all new protocol submissions. The VA research personnel lists are verified with the Research Service Personnel Database or by the WOC/Research Personnel Coordinator at the time of submission.
- b. *Continuing review* - The Human Subjects Protocol Management Administrator is provided a research personnel list by the PI as part of the continuing review process. All research personnel must maintain active research privileges in order to continue work on a VA protocol. The VA research personnel lists are verified with the Research Service Personnel Database or by the WOC/Research Personnel Coordinator at the time of submission.
- c. *Amendments* – The Human Subjects Protocol Management Administrator is provided a personnel list via an IRB amendment. The administrator reconciles the IRB personnel list with the VA research personnel list. The VA research personnel lists are verified with the Research Service Personnel Database or by the WOC/Research Personnel Coordinator at the time of submission.

- d. *Personnel Initiated* – Research personnel requiring research privileges may directly contact the WOC/Research Personnel Coordinator or be referred to the WOC/Research Personnel Coordinator by other R&D office staff.

4. **DATABASES.** The following Microsoft Access® databases are utilized within the R&D Office to communicate and track information required for granting VA research privileges and approval of research individuals assigned to VA-approved research protocols.

a. Research Service Personnel Database

1. **Purpose.** This database contains documentation of information required for granting research privileges. The database contains the following information: current status (active, pending, or inactive), eligibility (human, animal, lab, human/animal, human/lab, human/animal/lab, animal/lab, lab, admin, R&D com), appointment type (WOC, VA, Resident, Exempt), human category (VA salaried, VA salaried MD, WOC, WOC MD, Exempt, other, contract status, education,), admin category (admin, committee member, foundation admin), lab category (on-site, off-site non-VA funded, off-site VA funded), animal category, duty location, name, supervisor, position, degree, license type, license verification date, service, phone number, email, education verification date, MSO board action expiration date, VetPro completion date, WOC start date, WOC end date, scope of practice/work (yes, no), date scope approved, IPA approval date, COI approval date, COI disclosure (yes, no), CITI training date, Information Security Awareness Training date, Privacy Training date, Information Security 201 Training date, Biosecurity Training date, SLA request (yes, no).
2. **Maintenance.** The WOC/Research Personnel Coordinator maintains and updates this database daily as information is gathered. All information required for granting VA research privileges is verified initially and the following information will be queried within the database at the specified time interval to ensure that this information is always current and complete:
 - i. **WOC Status**
 - a. Expires every two years, unless specified otherwise
 - b. Query monthly projecting two months out to ensure timely notification to the researcher and notification to HR for renewals.
 - ii. **CITI Training Modules**
 - a. Individuals involved in human subjects projects must complete training in GCP and the ethical principles on which human research is to be conducted before they may participate in human subjects research

- b. The VA has made available an on-line course that effectively communicates the ethical principles and acceptable practices for human subject's research. Completion of this course satisfies the VA human research training requirement. Current instructions can be found at <https://www.citiprogram.org/default.asp>
- c. In addition to individuals involved in the direct conduct of research involving human subjects, CITI training must be completed by research office staff involved with human subjects project submissions (exclusive of secretarial support) and all members of the R&D Committee and subcommittees that review human subjects research.
- d. Human subjects training must be updated every 2 years thereafter. SCTVHCS defines "every 2 years" as within 730 days after the previous training.
- e. Query monthly projecting one month out ensuring timely notification to the researcher to update required training.

iii. LMS Training Modules (VHA Privacy Policy, Information Security Awareness)

- a. Expires every year
- b. Query monthly projecting one month out ensuring timely notification to the researcher for renewals.

iv. Medical Staff Offices (MSO) Privileges

- a. Expires at variable intervals
- b. Query monthly and verify the MSO office has recertified privileges and posted updates on their SharePoint.

b. Research Participant Database

1. Purpose. This database contains documentation of information required for tracking VA research personnel that are currently participating in specific VA-approved human subjects protocols. R&D Committee approval of a protocol involving human subjects cannot be granted unless the assigned PI has active research privileges. Research personnel listed on a human subjects protocol may not participate in VA research activities without active research privileges.

- i. Queries are generated with the following information: Name, degree, role, investigator, project #, current status, exempt status for the individual protocol (entered at the time of the query) , CITI training date
- ii. A PI for a human subjects protocol may include VA salaried or WOC appointed credentialed individuals. Students and other trainees (including residents and fellows) may participate in human subjects protocols as research staff or co-investigators but may not serve in the

role of a principal investigator. A researcher sufficiently experienced in the area of the trainee's research interest must serve as the principal investigator and is responsible for oversight of the research and trainee.

2. **Maintenance.** The Human Subjects Protocol Management Administrator maintains and updates this database regularly. The Research Participants Database queries information from the Research Service Personnel Database.

5. GRANTING OF RESEARCH PRIVILEGES BY THE WOC/RESEARCH PERSONNEL COORDINATOR

- a. During the initial meeting, the WOC/Research Personnel Coordinator provides research personnel with a questionnaire titled "Application for VA research Privileges – Initial Processing Checklist." The questionnaire contains questions that will help the WOC/Research Personnel Coordinator determine how the prospective research personnel will be categorized and processed.
- b. Research personnel may be granted eligibility status for human, animal, lab, human/animal, human/lab, human/animal/lab, animal/lab, lab, admin, or R&D Committee.
- c. Research personnel conducting HUMAN subjects research are categorized and processed as one of five categories:
 1. *VA Salaried, U.S. Licensed Physicians*
 2. *Non VA Salaried, U.S. Licensed Physicians (contract, fee basis, WOC)*
 3. *VA-affiliated fellows, med students, residents (Education Service)*
 4. *Other*
 - a) non-physician licensed providers, non-physician unlicensed providers
 - b) unlicensed physicians
 5. unlicensed research personnel
- d. *Exempt Personnel* The following information is required for granting of research privileges to research personnel conducting HUMAN subjects research, according to how they are categorized:
 1. *VA Salaried, U.S. Licensed Physicians*
 - i. Documentation of VA "Human Subjects Protection and Good Clinical Practices Training" (CITI)

- a. Research personnel must affiliate with the South Texas Veteran Health Care System when setting up and completing this CITI module.
 - b. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
- ii. VA Data Security Trainings (LMS)
 - a. Research personnel complete the following LMS modules after LMS access is initiated by the WOC/Research Personnel Coordinator:
 - 1. VHA Privacy Policy
 - 2. Information Security Awareness
 - 3. Information Security 201 for R&D Personnel
 - b. Information Security 201 for R&D Personnel is loaded in LMS by the WOC/Research Personnel Coordinator.
 - c. VHA Privacy Policy instructions (VA 58879) and Information Security Awareness training is assigned to personnel by the WOC/Research Personnel Coordinator and automatically loaded in LMS within 24 hours of registration and available for personnel to complete.
 - d. VHA Privacy Policy (VA 10203) training is loaded when VA58879 appears by the WOC/Research Personnel Coordinator. The VA 58879 date is applied to VA 10203 to ensure the appropriate training is completed.
 - e. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database
- iii. Education verification
 - a. Medical Staff Office (MSO)/ VetPro verifies education upon initial appointment.
 - b. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of MSO privileging.
- iv. License verification
 - a. Medical Staff Office (MSO)/ VetPro verifies licensure upon initial appointment and at the time of expiration.

- b. License verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of MSO privileging.
 - v. List of Excluded Individuals/Entities (LEIE), search <http://exclusions.oig.hhs.gov/>
 - a. Medical Staff Office (MSO)/ VetPro verifies LEIE upon initial appointment
 - vi. Research Financial Conflict of Interest (COI) Statement
 - a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of Financial Conflict of Interest Administrator.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - d. If a COI is disclosed this is noted in the Research Service Personnel Database by the WOC/Research Personnel Coordinator with a date of the management plan (MPL).
 - vii. Board Action (credentialing & privileging verification)
 - a. The WOC/Research Personnel Coordinator verifies credentialing and privileging by documenting the date Medical Staff Office (MSO) issued the board action and the date the action expires within the Research Service Personnel Database.
- 2. *Non VA Salaried, U.S. Licensed Physicians* (contract, fee basis, WOC)
 - i. Documentation of VA “Human Subjects Protection and Good Clinical Practices Training” (CITI)
 - a. Research personnel must affiliate with the South Texas Veteran Health Care System when setting up and completing this CITI module.
 - b. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - ii. VA Data Security Trainings (LMS)
 - a. Research personnel complete the following LMS modules after LMS access is initiated by the WOC/Research Personnel Coordinator:

1. VHA Privacy Policy
2. Information Security Awareness
3. Information Security 201 for R&D Personnel

b. Information Security 201 for R&D Personnel is loaded in LMS by the WOC/Research Personnel Coordinator.

c. VHA Privacy Policy and Information Security Awareness training is assigned to personnel by the WOC/Research Personnel Coordinator and automatically loaded in LMS within 24 hours of registration and available for personnel to complete.

d. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.

iii. Education verification

a. Medical Staff Office (MSO)/ VetPro verifies education upon initial appointment.

b. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of MSO privileging.

iv. License verification

a. Medical Staff Office (MSO)/ VetPro verifies licensure upon initial appointment and at the time of expiration.

b. License verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of MSO privileging.

v. List of Excluded Individuals/Entities (LEIE), search <http://exclusions.oig.hhs.gov/>

a. Medical Staff Office (MSO)/ VetPro verifies LEIE upon initial appointment

vi. Research Financial Conflict of Interest (COI) Statement

a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator.

b. The WOC/Research Personnel Coordinator routes this for review and signature of Financial Conflict of Interest Administrator.

c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.

- d. If a COI is disclosed this is noted in the Research Service Personnel Database by the WOC/Research Personnel Coordinator.
 - vii. Board Action (credentialing & privileging verification)
 - a. The WOC/Research Personnel Coordinator verifies credentialing and privileging by documenting the date Medical Staff Office (MSO) issued the board action and the date the action expires within the Research Service Personnel Database.
 - viii. Signed Intellectual Property Agreement (IPA)
 - a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of ACOS for Research.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - ix. WOC appointment for RESEARCH Privileges
 - a. The WOC/Research Personnel Coordinator generates a WOC request memo to Human Resources (HR).
 - b. The WOC/Research Personnel Coordinator generates a STVHCS Medical Staff Member Appointment Request memo to MSO to add a WOC for Research to clinical credentialing status.
 - c. The WOC/Research Personnel Coordinator coordinates the WOC appointment through communication with research personnel, HR, MSO.
 - d. The WOC/Research Personnel Coordinator will document the WOC start and end date in the Research Service Personnel Database.
- 3. *VA-affiliated* fellows, med students, residents (Education Service)
 - i. Documentation of VA “Human Subjects Protection and Good Clinical Practices Training” (CITI)

- a. Research personnel must affiliate with the South Texas Veteran Health Care System when setting up and completing this CITI module.
 - b. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
- ii. VA Data Security Training (LMS)
 - a. VHA Privacy Policy and Information Security Awareness training is completed within education service and copies of the training dates are provided to the WOC/Research Personnel Coordinator.
 - b. Information Security 201 is completed at the following website <https://www.eeslearning.net/librix/loginhtml.asp?v=librix>The research personnel must bring a copy of the completed certificate to the WOC/Research Personnel Coordinator.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
- iii. Education verification
 - a. Education verifies education upon initial appointment.
 - b. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of acceptance into education program
- iv. License verification
 - a. Education verifies licensure upon initial appointment
 - b. License verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of acceptance into education program
- v. Research Financial Conflict of Interest (COI) Statement
 - a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of Financial Conflict of Interest Administrator.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database

- d. If a COI is disclosed this is noted in the Research Service Personnel Database by the WOC/Research Personnel Coordinator.
 - vi. Signed Intellectual Property Agreement (IPA)
 - a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of ACOS for Research.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database
 - vii. Scope of Practice
 - a. Research personnel complete this form with the guidance of their PI and return to the WOC/Research Personnel Coordinator for documentation after signature by PI/Supervising physicians.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of ACOS for Research and the Chief of Staff.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - viii. Copy of Education appointment memo (obtained from the VA Education Office x. 15109) which includes the expiration date of the program
 - a. The WOC/Research Personnel Coordinator will document the start and end dates within the WOC start and end date columns in the Research Service Personnel Database.
- 4. *Other* (non-physician licensed or unlicensed providers, unlicensed physicians, unlicensed research personnel)
 - i. Documentation of VA “Human Subjects Protection and Good Clinical Practices Training” (CITI)
 - a. Research personnel must affiliate with the South Texas Veteran Health Care System when setting up and completing this CITI module.
 - b. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.

- ii. VA Data Security Trainings (LMS)
 - a. Research personnel complete the following LMS modules after LMS access is initiated by the WOC/Research Personnel Coordinator:
 - 1. VHA Privacy Policy
 - 2. Information Security Awareness
 - 3. Information Security 201 for R&D Personnel
 - b. Information Security 201 for R&D Personnel is loaded in LMS by the WOC/Research Personnel Coordinator.
 - c. VHA Privacy Policy and Information Security Awareness training is assigned to personnel by the WOC/Research Personnel Coordinator and automatically loaded in LMS within 24 hours of registration and available for personnel to complete.
 - d. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.

- iii. Credentialing

- a. For unlicensed physicians the WOC/Research Personnel Coordinator verifies credentialing by documenting the date Medical Staff Office (MSO) issued the board action and the date the action expires within the Research Service Personnel Database.
- b. Although unlicensed physicians cannot be privileged, MSO must document lack of privileging via Board Action.
- c. For all non-physician licensed or unlicensed providers, the WOC/Research Personnel Coordinator verifies credentialing by documenting the date of HR/VetPro issued credentialing (date of the WOC approval or date specified by HR for VA salaried employees) within the Research Service Personnel Database

- iv. Education verification

- a. Medical Staff Office (MSO)/ VetPro verifies education upon initial appointment for all unlicensed physicians.
 - 1. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of MSO credentialing.
- b. HR/VetPro verifies education upon initial appointment for all non-physician licensed or unlicensed providers.

1. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of VetPro credentialing.
- c. WOC/Research Personnel Coordinator verifies education upon initial appointment for all unlicensed research personnel.
1. 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.
 2. If on-line verification is available for the educational institution, an electronic request will be initiated.
 3. 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.
 4. Education verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date education was verified or good faith attempt was completed
- v. License verification
- a. HR/ VetPro verifies licensure for all non-physician licensed personnel upon initial appointment and at the time of expiration.
 - b. License verification is documented by the WOC/Research Personnel Coordinator within the Research Service Personnel Database as the date of VetPro credentialing
- vi. LEIE, search <http://exclusions.oig.hhs.gov/>
- a. Medical Staff Office (MSO)/ VetPro or HR/VetPro verifies LEIE upon initial appointment
- vii. Research Financial Conflict of Interest (COI) Statement
- a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of Financial Conflict of Interest Administrator.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.

- d. If a COI is disclosed this is noted in the Research Service Personnel Database by the WOC/Research Personnel Coordinator.
- viii. Signed Intellectual Property Agreement (IPA)
 - a. All NON-VA salaried Research personnel complete this form and return to the WOC/Research Personnel Coordinator.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of ACOS for Research.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - d. For VA salaried Research personnel the WOC/Research Personnel Coordinator will document N/A in the Research Service Personnel Database
- ix. Scope of Practice
 - a. Research personnel complete this form with the guidance of their PI and return to the WOC/Research Personnel Coordinator for documentation after signature by PI/Supervising physicians.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of ACOS for Research and the Chief of Staff.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
- x. All NON- VA salaried complete a WOC appointment for RESEARCH Privileges
 - a. The WOC/Research Personnel Coordinator generates a WOC request memo to Human Resources (HR).
 - b. The WOC/Research Personnel Coordinator coordinates the WOC appointment through communication with research personnel, Human Resources (HR), Medical Staff Office.
 - c. The WOC/Research Personnel Coordinator will document the WOC start and end date in the Research Service Personnel Database.

5. *Exempt Personnel*

- i. Documentation of Information Security 201 for R&D Personnel training

- a. Information Security 201 is completed at the following website <https://www.eeslearning.net/librix/loginhtml.asp?v=librix>
 - b. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - c. Verification from PI denoting an exempt role in the study (documented on personnel form)
- ii. Research Financial Conflict of Interest (COI) Statement
- a. Research personnel complete this form and return to the WOC/Research Personnel Coordinator.
 - b. The WOC/Research Personnel Coordinator routes this for review and signature of Financial Conflict of Interest Administrator.
 - c. The WOC/Research Personnel Coordinator will document the date of completion in the Research Service Personnel Database.
 - d. If a COI is disclosed this is noted in the Research Service Personnel Database by the WOC/Research Personnel Coordinator.

6. REFERENCES: VHA Directive 1200; VHA Directive 2009-054; VHA Handbook 1100.19; VHA Directive 2006-067

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

8. RESCISSION: Research Service SOP 47 Verification of Education and Credentialing for Research Personnel; Research Policy 151-04 Without Compensation Appointments for Non-VA staff Conducting Research

9. RECERTIFICATION: March 2016


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Acting ACOS for Research and Development