

Research Program

Research Personnel - Without Compensation (WOC)

Standard Operating Procedure

OBJECTIVES:

- Research personnel must either be a VA paid employee or have a without compensation (WOC) appointment to the VA.
- Research personnel must be qualified for and work within their Scope of Practice.

BACKGROUND:

Without Compensation (WOC) appointments allow flexibility for staffing and collaboration on research studies while enabling the VA to ensure credentialing, qualifications, and trainings of collaborators and staff. WOC status also enables the VA to ensure compliance with VA policies such as intellectual property, data security, privacy of subjects, security of individually identifying information of subjects, etc.

A VA without compensation (WOC) appointment confers upon the appointee many privileges and responsibilities. A WOC appointment is a personnel appointment by which an individual contributes effort to VA activities but receives no monetary compensation from the VA. (VA considers WOC's to be federal employees.) (Referenced from the National Association of Veterans' Research and Education Foundations (NAVREF) Best Practices Program.)

A VA WOC appointment allows VA to accept donated services from individuals who are not paid by VA. A WOC appointment also limits VA liability for acts committed by WOC's to judgments under the Federal Tort Claims Act. (Referenced from the National Association of Veterans' Research and Education Foundations (NAVREF) Best Practices Program.)

WOC's are subject to federal conduct and conflicts of interest regulations in the performance of their official duties; must comply VA requirements pertaining to job qualifications and training; and VA can require them to assign to VA any rights to intellectual property that they may develop using VA resources. (Referenced from the National Association of Veterans' Research and Education Foundations (NAVREF) Best Practices Program.)

At the same time, subject to certification by the Attorney General, WOC's are protected by the Federal Tort Claims Act from personal liability in the performance of their official duties; may receive immunizations necessary to perform their work; and have access to VA employee assistance and training programs. (Referenced from the National Association of Veterans' Research and Education Foundations (NAVREF) Best Practices Program.)

DEFINITIONS:

Dayton VAMC Research Personnel - any individual, regardless of who pays their salary, who is engaged in Dayton VAMC research and who meets at least one of the following criteria:

- The person works on research project(s) on-site in Dayton VAMC sites (see definition below);
- Whose research work directly involves recruitment of or interaction with veterans within the Dayton VAMC;

- The person has regular verbal or physical contact with human participants in the Dayton VAMC system.

These individuals may include, but are not limited to principal investigators, sub-investigators, study coordinators, research assistants, data managers, lab personnel, pharmacy personnel, IRB staff, R&D

Committee members, and Research Office staff. These individuals do not include secretarial support staff.

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

Without Compensation (WOC) - status required for Dayton VAMC research personnel who are not VA-paid. Individuals who work off-site and who do not otherwise fit the definition of Dayton VAMC research personnel (above) do not need to obtain WOC appointments.

Dayton VAMC sites - locations where interactions with veterans, patients, samples and data can occur; sites are either VA property or VA-leased space.

RESPONSIBILITIES:

Principal investigators are responsible for:

- Ensuring that they and their staff have appropriate employment status at the Dayton VAMC.
- Ensuring that the employee/WOC is qualified for the job and that the employee/WOC works within his/her scope of practice.

The Dayton VAMC Research Office is responsible for notifying WOC staff of annual renewals and changes in WOC documentation.

PROCEDURES:

- See the definition of Dayton VAMC Research Personnel and Dayton VAMC site (above) to determine whether staff/collaborators fit the definition.
 - All research personnel who perform regular study-related activities at a Dayton VAMC site must be a VA-paid employee OR must obtain WOC status.
 - Research staff or collaborators, whose study-related activities/interactions are entirely off-site, do not need to be VA-paid employees or WOCs.
 - Off-site staff or collaborators:
 - Do not need WOC status.
 - Must be adequately trained and licensed, as attested to by the PI.
 - Must comply with VA rules with regard to data use and privacy issues.
- WOC:
 - If the staff/collaborator fits the definition and is not VA-paid and performs regular study-related activities at a Dayton VAMC site, then the staff/collaborator must obtain WOC status.
 - Applicants must report to the Research Office to obtain information on completing the WOC process. The following section titled "Without Compensation (WOC) Appointment" provides details on the documentation required by the Research Office.
- Scope of Practice: Principle Investigators must ensure that all WOC's working on under their supervision have an approved Scope of Practice that specifically defines their roles and responsibilities in the research protocol.

- Credentialing: If the applicant holds a degree that makes him/her eligible for licensure, registration or certification (even if he/she has chosen to not be licensed, registered, or certified), then he/she must complete VetPro. (This applies to physicians, physician assistants, nurse practitioners, registered nurses, licensed practical nurses, psychologists, and others).
- All VA-paid employees and WOC staff must complete Dayton VAMC mandatory trainings and must be able to produce proof of competency for all activities listed in their scope of practice document.

VA research may be conducted **only** by individuals who have an association with the VA through employment or a Without Compensation (WOC) appointment.

When the above have been completed (and the Research Compliance Officer has verified credentials), then the Research Office will submit a "WOC Appointment Request" letter to Police Service and Human Resources Management Service (HRMS). These Services will contact the applicant to make arrangements for completion of all necessary actions. Police Service will be responsible for fingerprinting, parking passes and the issuance of an identification badge. HRMS will be responsible for obtaining a background check (if longer than a six month appointment), initiating a physical (if applicable), final signature on the Memorandum of Agreement (MOA), as well as any additional requirements as set forth by VA and Medical Center policy.

When Police Service and HRMS actions have been completed, the Research Office will submit a "VISN 10 Unified Computer Access" form to the Information Security Officer (ISO) for review and signature. When approved, the ISO will submit this form to IRM for a computer access code.

When notified by HRMS that all the above has been completed, the Research Office will send a letter to the applicant and the PI informing them that the applicant may participate in research activities. A copy of this letter will be filed in the Research Office, sent to the Pharmacy (if the applicant's name is to be placed on the VA 10-9012 form), and also to the WSU IRB Coordinator for filing with their records. This letter will be signed by the Coordinator for Research or the Administrative Officer for Research.

**Dayton, Ohio VA Medical Center
Research Program**

WITHOUT COMPENSATION (WOC) APPOINTMENT

REQUIRED DOCUMENT CHECKLIST

- YES** WOC Employee Information Form

- YES** Curriculum Vitae (CV) (less than 6 months old)

- YES** Position Description/Statement of Work

- YES** Education Verification Form (Credentialing) – Release of Information
Consent

- YES** Scope of Practice Form (If applicable)

- YES** Memorandum of Agreement for a WOC Appointment

- YES** Conflict of Interest Form

- YES** Intellectual Property Agreement

- YES** Mandatory Training Verification

- YES** VISN 10 Unified Application for Computer Access

Return all completed documents to the Research Office (151). Police Service and Human Resources Management Service will contact you to schedule appointments to complete necessary actions.

Questions may be addressed to the Research Office at ext. 2194 or 1156.

**Dayton, Ohio VA Medical Center
Research Program**

WOC EMPLOYEE INFORMATION

Please make sure all information is legible

Employee Name _____
(print)

Supervisor/Principal Investigator _____

Title/Position _____

Are you, or are you able to be, licensed, registered or certified? ____ Yes ____ No
If yes, please explain (for credentialing purposes).

Home Address _____

Telephone (home) _____ (office) _____

Email Address _____

Social Security Number _____

Signature _____

VETPRO Required ____ Yes ____ No
(For Research Office only)

**Dayton, Ohio VA Medical Center
Research Program
Education Verification Form
Release of Information Consent**

As part of the credentialing process it is necessary to verify educational credentials.
To assist us in completing this process, please provide the following information.

Employee: First Name Middle Name Last Name	
University/Program Attended:	
Name Used when Attending School	
Employee: First Name Middle Name Last Name	
City/State/Country of University Attended	
Degree Title	Date Degree Awarded or Date Degree will be Awarded
Professional License/ Registration State (if applicable)	
Professional License Issue Date	Professional License Expiration Date
Social Security Number	Date of Birth
Employee Name	Employee Signature

Original Copy to Research Office

FOR OFFICE USE ONLY

Date of Verification	Degree/Certification Verified
Source of Verification	Verification Completed By

DAYTON VA MEDICAL CENTER
FINANCIAL CONFLICT OF INTEREST WORKSHEET

This document must be completed, signed and submitted by each Principal Investigator, Responsible Investigator, Co-Principal Investigator, Co-Investigator Collaborator, Study Coordinator and other research personnel who plan to devote effort to the proposed project. The information will be used only to review the proposed research project to which it applies. This completed and signed document must accompany the proposal to which it applies or the proposal will not be considered for further review.

Name:

Title of Research Proposal:

Role (check one): Principal Investigator Study Coordinator
 Responsible Investigator Collaborator
 Co-Investigator Other: _____
 Co-Principal Investigator

Percent effort on research protocol: %

1. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a business or other source related to the research proposal that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months? Yes No

If yes, explain source, value, and reason for compensation:

2. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee, or general partner own any patents that are related to the research project proposal? Yes No

If yes, please provide additional information below.

Patent number:

Date of Patent:

Title of Patent:

Have any active or pending license agreements been issued? Yes No

(If yes, attach a copy of each license.)

If yes, describe the period covered by each license and the projected royalty by year.

3. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own any provisional patents that are related to the research project proposal? Yes No

If yes, please provide additional information below.

Patent application number:

Date Filed:

Title of Provisional Patent:

Have any active or pending license agreements been issued? Yes No

(If yes, attach a copy of each license.)

If yes, describe the period covered by each license and the projected royalty by year.

4. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicly-traded company that may or may not own a patent that is related to the research project proposal? Yes No

If yes, what is the value of the stock/stock options? \$

Does this value represent more than a 5% ownership of the company? Yes No

5. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a publicly-traded company that may or may not own a patent that is related to the research project proposal and is valued at more than \$10,000 (or value is projected to exceed \$10,000 in the next 12 months)? Yes No

If yes, what is the value of the stock/stock options? \$

Does this value represent more than a 5% ownership of the company? Yes No

6. Please describe any of your VA duties that involve management of research projects or contracts other than those on which you are a principal investigator, responsible investigator, co-principal investigator, investigator, study coordinator or other research personnel. This includes oversight, approval, advising, recommending, or initiating actions on research related projects.

I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete, and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001). Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or up to one year following completion of this protocol, I will notify the R&D Committee promptly.

Signature

Date

This Financial Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest: has have not been identified for this investigator on this research protocol.

If a conflict of interest has been identified, the following actions are recommended:

Signature of Conflict of Interest Administrator

Date

**Dayton, Ohio VA Medical Center
Research Program**

VA WOC APPOINTEE INTELLECTUAL PROPERTY AGREEMENT

Please complete the following new VA-WOC Appointee Intellectual Property Agreement developed by the VA Office of General Counsel. Effective October 1, 2001, this document must be executed for new WOC's conducting research in our facility. In addition, the document must be executed at the time WOC's are renewed. The document provides advance information about their rights and responsibilities as it relates to any intellectual property developed in a VA facility.

**Dayton, Ohio VA Medical Center
Research Program**

VA-WOC APPOINTEE INTELLECTUAL PROPERTY AGREEMENT

This agreement is made between (Insert full name here) and the Department of Veterans Affairs (VA) in consideration of my without compensation (WOC) appointment by the Dayton, Ohio VA Medical Center (VAMC) and performing VA-Approved Research (as defined below) utilizing VA resources. This agreement is not intended to be executed by WOC appointees exclusively performing clinical services, attending services, or educational activities at the VAMC.

1. I hold a WOC appointment at the Dayton, Ohio VA Medical Center for the purpose of performing research projects, evaluated and approved by the Research and Development Committee (VA-Approved Research), at that VAMC.
2. By signing this agreement, I understand that, except as provided herein, I am adding no employment obligations to the VA beyond those created when I executed the WOC appointment.
3. I have read and understand the VHA Intellectual Property Handbook 1200.18 available at http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=403, which provides guidance and instruction regarding invention disclosures, patenting and the transfer of new scientific discoveries.
4. Notwithstanding that I am an employee or appointee at the Dayton, Ohio VA Medical Center, I will disclose to VA any invention that I make while acting within my VA-WOC appointment in the performance of VA-Approved Research utilizing VA resources at the VAMC or in VA-approved space.
5. I understand that the VA Office of General Counsel (OGC) will review the invention disclosure and will decide whether VA can and will assert an ownership interest. Every effort will be made to issue a decision within 40 days of receipt of a complete file. OGC will base its decision on whether VA has made a significant contribution to the invention, to include my use of VA facilities, VA equipment, VA materials, VA supplies, and VA personnel, as well as assessment of the potential of the invention.
6. If VA asserts an ownership interest based on my inventive contribution, then, subject to Paragraph 7 below, I agree to assign certain ownership rights I may have in such invention to the VA. I agree to cooperate with VA, when requested, in drafting the patent applications(s) for such invention and will thereafter sign any documents, recognizing VA's ownership, as required by the U.S. Patent and Trademark Office at the time the patent application is filed.
7. VA recognizes that I am employed or appointed at the entity named in paragraph 4 and have obligations to disclose and assign certain invention rights to it. If that entity asserts an ownership interest, VA will cooperate with it to manage the development of the invention as appropriate.
8. If a Cooperative Technology Administration Agreement (CTAA) exists between the VA and the mentioned entity in paragraph 4, this Agreement will be implemented in accordance with the provisions of that CTAA.

Signature

Date

Coordinator for Research

Date

PRE-EMPLOYMENT FINGERPRINT CHECK LIST

FULL NAME:

SOCIAL SECURITY NUMBER:

DATE OF BIRTH:

RACE:

EYE COLOR:

HAIR COLOR:

HEIGHT:

WEIGHT:

PLACE OF BIRTH (CITY/STATE):

COMPLETE RESIDENT ADDRESS:

CITIZENSHIP:

VETERAN SERVICE (I.E. US ARMY)

SERVICE ASSIGNED:

POSITION TITLE:

**(Medical Student, M.D., D.O., O.D., Program Support Assistant, etc)
It is required that we know what your position title is.**



DEPARTMENT OF VETERANS AFFAIRS

VISN 10 UNIFIED APPLICATION FOR COMPUTER ACCESS

ACTION: [] NEW USER [] RE-ACTIVATION APPLICANT'S HOME STATION:

REQUEST ACCESS TO: [] DAYTON [] CINCINNATI [] CHILLICOTHE [] CLEVELAND [] COLUMBUS

NAME: (Print) Last, First, MI SS#: - - PHONE: _____

ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

DOB: _____ FEMALE: [] MALE: [] TITLE: _____

SERVICE: _____ SECTION: _____ MAIL CODE: _____

PERSON CLASS: _____ USER CLASS: _____

EMPLOYMENT STATUS: [] PERMANENT [] TEMPORARY [] WOC Expiration Date: _____

[] NT DOMAIN ACCESS [] EXCHANGE E-MAIL [] VPN [] PKI [] VISTA

NT Username: VHA E-mail address: _____ @ _____

PRIMARY MENU: _____ SECURITY KEYS: _____

SECONDARY MENUS: _____

MAIL GROUPS: _____

JUSTIFICATION FOR ACCESS:

I CERTIFY that I have received VA Cyber Security and Privacy training and agree to abide by all applicable rules and regulations governing the use of VA Information and Automated Information Systems.

APPLICANT'S SIGNATURE:

Signature _____ Date _____

SERVICE CHIEF OR ADPAC SIGNATURE:

I certify the above employee is required to have this access

Signature _____ Date _____

to perform the duties assigned to them.

Print name _____ Phone # _____

CONCURRENCE BY ISO:

Requesting facility's ISO concurrence required on all inter-facility requests for access.

Signature _____ Date _____ Print name _____ Phone # _____

DO NOT WRITE BELOW THIS LINE! Process local requests IAW local policies. Remote access must process through the facility ISO.

CONCURRENCE BY:

Access station's ISO concurrence required on all inter-facility requests for access.

Signature/Title _____ Date _____

Director or Sponsoring Service Chief

Signature/Title _____ Date _____

INFORMATION RESOURCES MANAGEMENT:

DATE ACCOUNT ESTABLISHED ____/____/____

ESTABLISHED BY: _____ IF DENIED: _____

Department of Veterans Affairs (VA) National Rules of Behavior

I understand, accept, and agree to the following terms and conditions that apply to my access to, and use of, information, including VA sensitive information, or information systems of the U.S. Department of Veterans Affairs.

1. GENERAL RULES OF BEHAVIOR

a. I understand that when I use any Government information system, I have NO expectation of Privacy in VA records that I create or in my activities while accessing or using such information system.

b. I understand that authorized VA personnel may review my conduct or actions concerning VA information and information systems, and take appropriate action. Authorized VA personnel include my supervisory chain of command as well as VA system administrators and Information Security Officers (ISOs). Appropriate action may include monitoring, recording, copying, inspecting, restricting access, blocking, tracking, and disclosing information to authorized Office of Inspector General (OIG), VA, and law enforcement personnel.

c. I understand that the following actions are prohibited: unauthorized access, unauthorized uploading, unauthorized downloading, unauthorized changing, unauthorized circumventing, or unauthorized deleting information on VA systems, modifying VA systems, unauthorized denying or granting access to VA systems, using VA resources for unauthorized use on VA systems, or otherwise misusing VA systems or resources. I also understand that attempting to engage in any of these unauthorized actions is also prohibited.

d. I understand that such unauthorized attempts or acts may result in disciplinary or other adverse action, as well as criminal, civil, and/or administrative penalties. Depending on the severity of the violation, disciplinary or adverse action consequences may include: suspension of access privileges, reprimand, suspension from work, demotion, or removal. Theft, conversion, or unauthorized disposal or destruction of Federal property or information may also result in criminal sanctions.

e. I understand that I have a responsibility to report suspected or identified information security incidents (security and privacy) to my Operating Unit's Information Security Officer (ISO), Privacy Officer (PO), and my supervisor as appropriate.

f. I understand that I have a duty to report information about actual or possible criminal violations involving VA programs, operations, facilities, contracts or information systems to my supervisor, any management official or directly to the OIG, including reporting to the OIG Hotline. I also understand that I have a duty to immediately report to the OIG any possible criminal matters involving felonies, including crimes involving information systems.

g. I understand that the VA National Rules of Behavior do not and should not be relied upon to create any other right or benefit, substantive or procedural, enforceable by law, by a party to litigation with the United States Government.

h. I understand that the VA National Rules of Behavior do not supersede any local policies that provide higher levels of protection to VA's information or information systems. The VA National Rules of Behavior provide the minimal rules with which individual users must comply.

i. I understand that if I refuse to sign this VA National Rules of Behavior as required by VA policy, I will be denied access to VA information and information systems. Any refusal to sign the VA National Rules of Behavior may have an adverse impact on my employment with the Department.

2. SPECIFIC RULES OF BEHAVIOR.

a. I will follow established procedures for requesting access to any VA computer system and for notification to the VA supervisor and the ISO when the access is no longer needed.

b. I will follow established VA information security and privacy policies and procedures.

c. I will use only devices, systems, software, and data which I am authorized to use, including complying with any software licensing or copyright restrictions. This includes downloads of software offered as free trials, shareware or public domain.

d. I will only use my access for authorized and official duties, and to only access data that is needed in the fulfillment of my duties except as provided for in VA Directive 6001, Limited Personal Use of Government Office Equipment Including Information Technology. I also agree that I will not engage in any activities prohibited as stated in section 2c of VA Directive 6001.

e. I will secure VA sensitive information in all areas (at work and remotely) and in any form (e.g. digital, paper etc.), to include mobile media and devices that contain sensitive information, and I will follow the mandate that all VA sensitive information must be in a protected environment at all times or it must be encrypted (using FIPS 140-2 approved encryption). If clarification is needed whether or not an environment is adequately protected, I will follow the guidance of the local Chief Information Officer (CIO).

f. I will properly dispose of VA sensitive information, either in hardcopy, softcopy or electronic format, in accordance with VA policy and procedures.

g. I will not attempt to override, circumvent or disable operational, technical, or management security controls unless expressly directed to do so in writing by authorized VA staff.

h. I will not attempt to alter the security configuration of government equipment unless authorized. This includes operational, technical, or management security controls.

i. I will protect my verify codes and passwords from unauthorized use and disclosure and ensure I utilize only passwords that meet the VA minimum requirements for the systems that I am authorized to use and are contained in Appendix F of VA Handbook 6500.

j. I will not store any passwords/verify codes in any type of script file or cache on VA systems.

k. I will ensure that I log off or lock any computer or console before walking away and will not allow another user to access that computer or console while I am logged on to it.

l. I will not misrepresent, obscure, suppress, or replace a user's identity on the Internet or any VA electronic communication system.

m. I will not auto-forward e-mail messages to addresses outside the VA network.

n. I will comply with any directions from my supervisors, VA system administrators and information security officers concerning my access to, and use of, VA information and information systems or matters covered by these Rules.

o. I will ensure that any devices that I use to transmit, access, and store VA sensitive information outside of a VA protected environment will use FIPS 140-2 approved encryption (the translation of data into a form that is unintelligible without a deciphering mechanism). This includes laptops, thumb drives, and other removable storage devices and storage media (CDs, DVDs, etc.).

p. I will obtain the approval of appropriate management officials before releasing VA information for public dissemination.,

q. I will not host, set up, administer, or operate any type of Internet server on any VA network or attempt to connect any personal equipment to a VA network unless explicitly authorized **in writing** by my local CIO and I will ensure that all such activity is in compliance with Federal and VA policies.

r. I will not attempt to probe computer systems to exploit system controls or access VA sensitive data for any reason other than in the performance of official duties. Authorized penetration testing must be approved in writing by the VA CIO.

s. I will protect Government property from theft, loss, destruction, or misuse. I will follow VA policies and procedures for handling Federal Government IT equipment and will sign for items provided to me for my exclusive use and return them when no longer required for VA activities.

t. I will only use virus protection software, anti-spyware, and firewall/intrusion detection software **authorized by the VA** on VA equipment or on computer systems that are connected to any VA network.

u. If authorized, by waiver, to use my own personal equipment, I must use VA approved virus protection software, anti-spyware, and firewall/intrusion detection software and ensure the software is configured to meet VA configuration requirements. My local CIO will confirm that the system meets VA configuration requirements prior to connection to VA's network.

v. I will never swap or surrender VA hard drives or other storage devices to anyone other than an authorized OI&T employee at the time of system problems.

w. I will not disable or degrade software programs used by the VA that install security software updates to VA computer equipment, to computer equipment used to connect to VA information systems, or to create, store or use VA information.

x. I agree to allow examination by authorized OI&T personnel of any personal IT device [Other Equipment (OE)] that I have been granted permission to use, whether remotely or in any setting to access VA information or information systems or to create, store or use VA information.

y. I agree to have all equipment scanned by the appropriate facility IT Operations Service prior to connecting to the VA network if the equipment has not been connected to the VA network for a period of more than three weeks.

z. I will complete mandatory periodic security and privacy awareness training within designated timeframes, and complete any additional required training for the particular systems to which I require access.

aa. I understand that if I must sign a non-VA entity's Rules of Behavior to obtain access to information or information systems controlled by that non-VA entity, I still must comply with my responsibilities under the VA National Rules of Behavior when accessing or using VA information or information systems. However, those Rules of Behavior apply to my access to or use of the non-VA entity's information and information systems as a VA user.

bb. I understand that remote access is allowed from other Federal government computers and systems to VA information systems, subject to the terms of VA and the host Federal agency's policies.

cc. I agree that I will directly connect to the VA network whenever possible. If a direct connection to the VA network is not possible, then I will use VA-approved remote access software and services. I must use VA-provided IT equipment for remote access when possible. I may be permitted to use non-VA IT equipment [Other Equipment (OE)] only if a VA-CIO-approved waiver has been issued and the equipment is configured to follow all VA security policies and requirements. I agree that VA OI&T officials may examine such devices, including an OE device operating under an approved waiver, at any time for proper configuration and unauthorized storage of VA sensitive information.

dd. I agree that I will not have both a VA network connection and any kind of non-VA network connection (including a modem or phone line or wireless network card, etc.) physically connected to any computer at the same time unless the dual connection is explicitly authorized in writing by my local CIO.

ee. I agree that I will not allow VA sensitive information to reside on non-VA systems or devices unless specifically designated and approved in advance by the appropriate VA official (supervisor), and a waiver has been issued by the VA's CIO. I agree that I will not access, transmit or store remotely any VA sensitive information that is not encrypted using VA approved encryption.

ff. I will obtain my VA supervisor's authorization, in writing, prior to transporting, transmitting, accessing, and using VA sensitive information outside of VA's protected environment.

gg. I will ensure that VA sensitive information, in any format, and devices, systems and/or software that contain such information or that I use to access VA sensitive information or information systems are adequately secured in remote locations, e.g., at home and during travel, and agree to periodic VA inspections of the devices, systems or software from which I conduct access from remote locations. I agree that if I work from a remote location pursuant to an approved telework agreement with VA sensitive information that authorized OI&T personnel may periodically inspect the remote location for compliance with required security requirements.

hh. I will protect sensitive information from unauthorized disclosure, use, modification, or destruction, including using encryption products approved and provided by the VA to protect sensitive data.

ii. I will not store or transport any VA sensitive information on any portable storage media or device unless it is encrypted using VA approved encryption.

jj. I will use VA-provided encryption to encrypt any e-mail, including attachments to the e-mail, that contains VA sensitive information before sending the e-mail. I will not send any e-mail that contains VA

sensitive information in an unencrypted form. VA sensitive information includes personally identifiable information and protected health information.

kk. I may be required to acknowledge or sign additional specific or unique rules of behavior in order to access or use specific VA systems. I understand that those specific rules of behavior may include, but are not limited to, restrictions or prohibitions on limited personal use, special requirements for access or use of the data in that system, special requirements for the devices used to access that specific system, or special restrictions on interconnections between that system and other IT resources or systems.

3. Acknowledgement and Acceptance

- a. I acknowledge that I have received a copy of these Rules of Behavior.
- b. I understand, accept and agree to comply with all terms and conditions of these Rules of Behavior.

Print or type your full name

Signature

Date

Position Title

Office Phone

If you agree to these conditions, please sign the statement below and return the letter directly to the Research Office.

Either party may terminate this agreement at any time by written notice of such intent.

Jack Bernstein, M.D.
Coordinator for Research

I agree to serve in the above capacity under the conditions indicated.

Signature

Date

Position Statement of Work

Please write out a brief description of your position and duties on this research study.

Dayton VA Medical Center
Scope of Practice for Research Personnel

Please Print

Research Staff Member Name & Job Title	Dayton VAMC Credentialing (Internal Use Only)
	From: _____ To: _____
Licensed or Eligible for License YES NO	WOC Period (Internal Use Only)
<input type="checkbox"/> MD <input type="checkbox"/> NP <input type="checkbox"/> RN <input type="checkbox"/> None <input type="checkbox"/> Other, List below <input type="checkbox"/> WSU Resident <hr/>	From: _____ To: _____
Principal Investigator (PI)	Immediate Supervisor
Salary Source	CPRS Access Requested
<input type="checkbox"/> VA <input type="checkbox"/> WSU <input type="checkbox"/> CFBRE <input type="checkbox"/> Other, List below <hr/>	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, please attach Computer Access Request form.

The Scope of Practice is specific to the duties and responsibilities of the Research Staff member named above as an agent of the listed Principal Investigator(s), and/or alternate supervisor for one year. As such he/she is specifically authorized to conduct research with the responsibilities outlined below in conjunction with approved research protocols. This document does not waive the responsibility to secure Dæ q } Á/A clinical privileges for any licensed independent provider under VHA Directive 1100.19 Credentialing & Privileging or nursing credentialing and boarding process. The Principal Investigator remains responsible at all times for the conduct of the employee and must complete, sign and date this Scope of Practice.

PROCEDURES:

A research employee may be authorized to perform the following duties and procedures on a regular and ongoing basis. They may be performed without specific prior discussion/instructions from the Principal Investigator. The Principal Investigator **must initial** whether or not the research employee is granted each duty listed below. A signed/dated copy of this document will be maintained in the Research Office.

Section I. HUMAN RESEARCH DUTIES <input type="checkbox"/> N/A, Proceed to Section II	Granted	Not Granted
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	<input type="checkbox"/>	<input type="checkbox"/>
Develops recruitment methods to be utilized in the study.	<input type="checkbox"/>	<input type="checkbox"/>
Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies).	<input type="checkbox"/>	<input type="checkbox"/>
Initiates submission of regulatory documents to IRB, VA R&D committee and sponsor.	<input type="checkbox"/>	<input type="checkbox"/>
Prepares study initiation activities.	<input type="checkbox"/>	<input type="checkbox"/>
Provides education and instruction of study medication use, administration, storage, side effects and notifies adverse drug reactions to study site.	<input type="checkbox"/>	<input type="checkbox"/>
Provides education regarding study activities to patient, relatives and Medical Center staff as necessary per protocol.	<input type="checkbox"/>	<input type="checkbox"/>
Maintains complete and accurate data collection in case report forms and source documents.	<input type="checkbox"/>	<input type="checkbox"/>
Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	<input type="checkbox"/>	<input type="checkbox"/>
Obtains and organizes data such as tests results, diaries/cards or other necessary information for the study.	<input type="checkbox"/>	<input type="checkbox"/>
Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc.	<input type="checkbox"/>	<input type="checkbox"/>
Accesses patient medical information while maintaining patient confidentiality.	<input type="checkbox"/>	<input type="checkbox"/>
Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".	<input type="checkbox"/>	<input type="checkbox"/>
Initiates intravenous (IV) therapy and Administers IV solutions and medications.	<input type="checkbox"/>	<input type="checkbox"/>
Drug Accountability: Obtains study drugs from research pharmacy after order by licensed provider. Delivers/administers study drug to research participant.	<input type="checkbox"/>	<input type="checkbox"/>

Section II.	Granted	Not Granted
HUMAN DATA DUTIES <input type="checkbox"/> N/A, Proceed to Section III		
Organizing, filing and analyzing human subject data.	<input type="checkbox"/>	<input type="checkbox"/>
Section III.	Granted	Not Granted
Specific Duties not specified above <input type="checkbox"/> N/A, Proceed to Section VII		
	<input type="checkbox"/>	<input type="checkbox"/>

Section IV.**Education Requirements:**

1. VA Research Certification in Human Subject Protection and Good Clinical Practice
 - a. CITI Program – www.citiprogram.org FOR ALL EMPLOYEES. THIS MUST BE COMPLETED ANNUALLY.
2. VA HIPAA/Privacy Training: THIS MUST BE COMPLETED ANNUALLY.
 - a. <https://www.lms.va.gov/plateau/user/login.jsp> VA paid employees only.
 - b. <https://www.ees-learning.net> for all non-VA paid employees.
3. VA Information Security Awareness Training: THIS MUST BE COMPLETED ANNUALLY.
 - a. <https://www.lms.va.gov/plateau/user/login.jsp> for all VA paid employees only.
 - b. <https://www.ees-learning.net> for all non-VA paid employees.

NOTICE TO LICENSED PROFESSIONALS:

Individuals found to be working outside their privileges as granted by the DVAMC will be subject to disciplinary action and possible reporting to the National Practitioner Data Bank.

RESEARCH EMPLOYEE'S STATEMENT:

This Scope of Practice outlines routine general duties I am permitted to undertake in conjunction with a VA approved protocol. I understand that all research must be approved by the WSU IRB and the Dayton VA R&D Committees. If I have questions or concerns, I am encouraged to contact the Research Compliance Officer or the R&D Office. I also understand that performing duties beyond this scope of practice without specific authorization may lead to disciplinary action. Both the principal investigator and I are familiar with all duties and procedures granted in this Scope of Practice. I agree to abide by the parameters of this Scope of Practice and all-applicable hospital policies and regulations.

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Research Employee's Signature

Date

PRINCIPAL INVESTIGATOR'S STATEMENT:

This Scope of Practice for _____ (*Research Staff Name*) was reviewed and discussed with the employee on the date shown below. After reviewing his/her education, competency, qualifications, research practice involving duties checked above, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties and procedures. Both the Research Staff Member and I are familiar with all duties and procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice and all-applicable hospital policies and regulations.

As a principal investigator, I further understand that conducting research without DVAMC R&D Committee or subcommittee approvals may affect my standing at the VA and that ethical breaches in the conduct of my research may affect my ability to do research with the VA in the future.

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A new Scope of Practice should be submitted every year and amended as necessary to reflect changes in the research staff member's duties and responsibilities and/or hospital or research policies.

Principal Investigator

Date

Annual Review	Date
PI Sign _____ Employee Sign _____	
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_____ Office Use Only _____	
INSTITUTIONAL APPROVALS:	
C/Research and Development _____	Date: _____