Ralph H. Johnson VA Medical Center

Research Service (151)

With Out Compensation Packet

If you have any questions please contact:

Charles Holloman
109 Bee Street
Charleston, SC 29401
(843) 789-6703
Charles.Holloman@va.gov

Once completed please return in person to:
VA R&D Office
Strom Thurmond Bldg.
Room 148

Revised July 13, 2015

Checklist
Appointment of Non-Physicians WOC

Please ensure the following items are included in the appointment package before returning to Research & Development

WOC Appointment Request Form (in packet)

Resume or Curriculum Vitae (CV) (not in packet must provide)

PPD / TB Test (not in packet must provide)

Declaration for Federal Employment OF-306 (in packet)

Scope of Research Practice for Research Personnel (in packet)

Job description (not in packet must provide)

Education Verification Form (in packet)

VAMC Identification Badge Form (in packet)

Fingerprint Information (in packet)

National Rules of Behavior (in packet)

Patient abuse form/memo (in packet)

Intellectual Property (in packet)

Required VA Research Training for Employees and WOCs (3)
Follow instructions

WOC APPOINTMENT REQUEST

(PLEASE PRINT)

PLEASE PROCESS THE FOLLOWING AS A WOC APPOINTMENT:

NAME: _____

DATE OF BIRTH: _____ COUNTRY OF BIRTH: _____

SOCIAL SECURITY NUMBER: _____

ARE YOU A CITIZEN OF THE UNITED STATES OF AMERICA? YES ☐ NO ☐

IF NO, OF WHAT COUNTRY OR COUNTRIES ARE YOU A CITIZEN? _____

_____

VISA TYPE / OR GREEN CARD: _____ VISA/GREEN CARD #: _____

VISA EXPIRATION DATE: _____

REQUESTED PERIOD OF APPOINTMENT: TENATIVE START DATE _____ TO _____

POSITION TITLE: _____

COMPUTER ACCESS: YES ☐ NO ☐ VISTA/CPRS: YES ☐ NO ☐

HOME ADDRESS: _____

CITY, STATE, ZIP CODE _____

HOME PHONE: _____ WORK PHONE: _____

E-MAIL ADDRESS: _____

CHECK IF YOUR POSITION IS EXPECTED TO HAVE CONTACT WITH:

HUMAN SUBJECTS ☐ ANIMAL SUBJECTS ☐

POSITION FUNDED BY (PLEASE CIRCLE): VISTAR MUSC CRI OTHER

POINT OF CONTACT NAME & EMAIL: _____

POINT OF CONTACT PHONE: _____

_____ _____

SIGNATURE OF SUPERVISOR DATE

_____

PRINT NAME OF SUPERVISOR/PI

Declaration for Federal Employment*

(*This form may also be used to assess fitness for federal contract employment)

Form Approved
OMB No. 3206-0182

Instructions

The information collected on this form is used to determine your acceptability for Federal and Federal contract employment and your enrollment status in the Government's Life Insurance program. You may be asked to complete this form at any time during the hiring process. Follow instructions that the agency provides. If you are selected, before you are appointed you will be asked to update your responses on this form and on other materials submitted during the application process and then to recertify that your answers are true.

All your answers must be truthful and complete. **A false statement on any part of this declaration or attached forms or sheets may be grounds for not hiring you, or for firing you after you begin work. Also, you may be punished by a fine or imprisonment (U.S. Code, title 18, section 1001).**

Either type your responses on this form or print clearly in dark ink. If you need additional space, attach letter-size sheets (8.5" X 11"). Include your name, Social Security Number, and item number on each sheet. We recommend that you keep a photocopy of your completed form for your records.

Privacy Act Statement

The Office of Personnel Management is authorized to request this information under sections 1302, 3301, 3304, 3328, and 8716 of title 5, U. S. Code. Section 1104 of title 5 allows the Office of Personnel Management to delegate personnel management functions to other Federal agencies. If necessary, and usually in conjunction with another form or forms, this form may be used in conducting an investigation to determine your suitability or your ability to hold a security clearance, and it may be disclosed to authorized officials making similar, subsequent determinations.

Your Social Security Number (SSN) is needed to keep our records accurate, because other people may have the same name and birth date. Public Law 104-134 (April 26, 1996) asks Federal agencies to use this number to help identify individuals in agency records. Giving us your SSN or any other information is voluntary. However, if you do not give us your SSN or any other information requested, we cannot process your application. Incomplete addresses and ZIP Codes may also slow processing.

ROUTINE USES: Any disclosure of this record or information in this record is in accordance with routine uses found in System Notice OPM/GOVT-1, General Personnel Records. This system allows disclosure of information to: training facilities; organizations deciding claims for retirement, insurance, unemployment, or health benefits; officials in litigation or administrative proceedings where the Government is a party; law enforcement agencies concerning a violation of law or regulation; Federal agencies for statistical reports and studies; officials of labor organizations recognized by law in connection with representation of employees; Federal agencies or other sources requesting information for Federal agencies in connection with hiring or retaining, security clearance, security or suitability investigations, classifying jobs, contracting, or issuing licenses, grants, or other benefits; public and private organizations, including news media, which grant or publicize employee recognitions and awards; the Merit Systems Protection Board, the Office of Special Counsel, the Equal Employment Opportunity Commission, the Federal Labor Relations Authority, the National Archives and Records Administration, and Congressional offices in connection with their official functions; prospective non-Federal employers concerning tenure of employment, civil service status, length of service, and the date and nature of action for separation as shown on the SF 50 (or authorized exception) of a specifically identified individual; requesting organizations or individuals concerning the home address and other relevant information on those who might have contracted an illness or been exposed to a health hazard; authorized Federal and non-Federal agencies for use in computer matching; spouses or dependent children asking whether the employee has changed from a self-and-family to a self-only health benefits enrollment; individuals working on a contract, service, grant, cooperative agreement, or job for the Federal government; non-agency members of an agency's performance or other panel; and agency-appointed representatives of employees concerning information issued to the employees about fitness-for-duty or agency-filed disability retirement procedures.

Public Burden Statement

Public burden reporting for this collection of information is estimated to vary from 5 to 30 minutes with an average of 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to the U.S. Office of Personnel Management, Reports and Forms Manager (3206-0182), Washington, DC 20415-7900. The OMB number, 3206-0182, is valid. OPM may not collect this information, and you are not required to respond, unless this number is displayed.

Declaration for Federal Employment*

Form Approved
OMB No. 3206-0182

(*This form may also be used to assess fitness for federal contract employment)

GENERAL INFORMATION

1. **FULL NAME** (Provide your full name. If you have only initials in your name, provide them and indicate "Initial only". If you do not have a middle name, indicate "No Middle Name". If you are a "Jr.," "Sr.," etc. enter this under Suffix. First, Middle, Last, Suffix)

♦

2. **SOCIAL SECURITY NUMBER**

♦

3a. **PLACE OF BIRTH** (Include city and state or country)

♦

3b. **ARE YOU A U.S. CITIZEN?**

☐ YES ☐ NO (If "NO", provide country of citizenship) ♦

4. **DATE OF BIRTH** (MM / DD / YYYY)

♦

5. **OTHER NAMES EVER USED** (For example, maiden name, nickname, etc)

♦

♦

6. **PHONE NUMBERS** (Include area codes)

Day ♦

Night ♦

Selective Service Registration

If you are a male born after December 31, 1959, and are at least 18 years of age, civil service employment law (5 U.S.C. 3328) requires that you must register with the Selective Service System, unless you meet certain exemptions.

7a. Are you a male born after December 31, 1959? ☐ YES ☐ NO (If "NO", proceed to 8.)

7b. Have you registered with the Selective Service System? ☐ YES (If "YES", proceed to 8.) ☐ NO (If "NO", proceed to 7c.)

7c. If "NO," describe your reason(s) in item 16.

Military Service

8. Have you ever served in the United States military? ☐ YES (If "YES", provide information below) ☐ NO

If you answered "YES," list the branch, dates, and type of discharge for all active duty.
If your only active duty was training in the Reserves or National Guard, answer "NO."

Branch	From (MM/DD/YYYY)	To (MM/DD/YYYY)	Type of Discharge

Background Information

For all questions, provide all additional requested information under item 16 or on attached sheets. The circumstances of each event you list will be considered. However, in most cases you can still be considered for Federal jobs.

For questions 9,10, and 11, your answers should include convictions resulting from a plea of *nolo contendere* (no contest), but omit (1) traffic fines of $300 or less, (2) any violation of law committed before your 16th birthday, (3) any violation of law committed before your 18th birthday if finally decided in juvenile court or under a Youth Offender law, (4) any conviction set aside under the Federal Youth Corrections Act or similar state law, and (5) any conviction for which the record was expunged under Federal or state law.

9. During the last 7 years, have you been convicted, been imprisoned, been on probation, or been on parole? (Includes felonies, firearms or explosives violations, misdemeanors, and all other offenses.) *If "YES," use item 16 to provide the date, explanation of the violation, place of occurrence, and the name and address of the police department or court involved.* ☐ YES ☐ NO

10. Have you been convicted by a military court-martial in the past 7 years? *(If no military service, answer "NO.") If "YES," use item 16 to provide the date, explanation of the violation, place of occurrence, and the name and address of the military authority or court involved.* ☐ YES ☐ NO

11. Are you currently under charges for any violation of law? *If "YES," use item 16 to provide the date, explanation of the violation, place of occurrence, and the name and address of the police department or court involved.* ☐ YES ☐ NO

12. During the last 5 years, have you been fired from any job for any reason, did you quit after being told that you would be fired, did you leave any job by mutual agreement because of specific problems, or were you debarred from Federal employment by the Office of Personnel Management or any other Federal agency? *If "YES," use item 16 to provide the date, an explanation of the problem, reason for leaving, and the employer's name and address.* ☐ YES ☐ NO

13. Are you delinquent on any Federal debt? (Includes delinquencies arising from Federal taxes, loans, overpayment of benefits, and other debts to the U.S. Government, plus defaults of Federally guaranteed or insured loans such as student and home mortgage loans.) *If "YES," use item 16 to provide the type, length, and amount of the delinquency or default, and steps that you are taking to correct the error or repay the debt.* ☐ YES ☐ NO

Declaration for Federal Employment*

Form Approved
OMB No. 3206-0182

(*This form may also be used to assess fitness for federal contract employment)

Additional Questions

14. Do any of your relatives work for the agency or government organization to which you are submitting this form? (Include: father, mother, husband, wife, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, father-in-law,mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, and half sister.) *If "YES," use item 16 to provide the relative's name,relationship, and the department, agency, or branch of the Armed Forces for which your relative works.* ☐ YES ☐ NO

15. Do you receive, or have you ever applied for, retirement pay, pension, or other retired pay based on military, Federal civilian, or District of Columbia Government service? ☐ YES ☐ NO

Continuation Space / Agency Optional Questions

16. Provide details requested in items 7 through 15 and 18c in the space below or on attached sheets. Be sure to identify attached sheets with your name, Social Security Number, and item number, and to include ZIP Codes in all addresses. If any questions are printed below, please answer as instructed *(these questions are specific to your position and your agency is authorized to ask them).*

Certifications / Additional Questions

APPLICANT: If you are applying for a position and have not yet been selected, carefully review your answers on this form and any attached sheets. When this form and all attached materials are accurate, read item 17, and complete 17a.

APPOINTEE: If you are being appointed, carefully review your answers on this form and any attached sheets, including any other application materials that your agency has attached to this form. If any information requires correction to be accurate as of the date you are signing, make changes on this form or the attachments and/or provide updated information on additional sheets, initialing and dating all changes and additions. When this form and all attached materials are accurate, read item 17, complete 17b, read 18, and answer 18a, 18b, and 18c as appropriate.

17. I **certify** that, to the best of my knowledge and belief, all of the information on and attached to this Declaration for Federal Employment, including any attached application materials, is true, correct, complete, and made in good faith . **I understand that a false or fraudulent answer to any question or item on any part of this declaration or its attachments may be grounds for not hiring me, or for firing me after I begin work, and may be punishable by fine or imprisonment. I understand** that any information I give may be investigated for purposes of determining eligibility for Federal employment as allowed by law or Presidential order. **I consent** to the release of information about my ability and fitness for Federal employment by employers, schools, law enforcement agencies, and other individuals and organizations to investigators, personnel specialists, and other authorized employees or representatives of the Federal Government. **I understand** that for financial or lending institutions, medical institutions, hospitals, health care professionals, and some other sources of information, a separate specific release may be needed, and I may be contacted for such a release at a later date.

17a. Applicant's Signature: _____ Date _____
(Sign in ink)

17b. Appointee's Signature: _____ Date _____
(Sign in ink)

Appointing Officer:
Enter Date of Appointment or Conversion
MM / DD / YYYY

18. **Appointee (Only respond if you have been employed by the Federal Government before):** Your elections of life insurance during previous Federal employment may affect your eligibility for life insurance during your new appointment. These questions are asked to help your personnel office make a correct determination.

18a. When did you leave your last Federal job? MM / DD / YYYY DATE:

18b. When you worked for the Federal Government the last time, did you waive Basic Life Insurance or any type of optional life insurance? ☐ YES ☐ NO ☐ DO NOT KNOW

18c. If you answered "YES" to item 18b, did you later cancel the waiver(s)? If your answer to item 18c is "NO," use item 16 to identify the type(s) of insurance for which waivers were not canceled. ☐ YES ☐ NO ☐ DO NOT KNOW

Ralph H. Johnson VAMC
Scope of Research Practice for Research Personnel

Name: _____

Service Line: _____

Principal Investigator/Primary Supervisor: _____

Alternate Supervisor (if applicable): _____

The Scope of Practice is specific to the duties and responsibilities of Research Personnel as an agent of the listed Principal Investigator (PI) and/or alternate supervisor. As such, he/she is specifically authorized to conduct research per the IRB and R&D approved protocol involving human subjects with the responsibilities outlined below, and under the supervision of the PI. The PI or supervisor must complete, sign, and date this Scope of Research Practice (SORP).

Please check: VA Paid____ WOC____ IPA____

Are you a Physician (MD or DO), Psychologist, Social Worker, Nurse (RN or LPN), Nurse Practioner, Physicians Assistant, Dentist, Podiatrist, or PharmD?

YES____ NO____

If yes, are you licensed in the U.S.? YES_____ NO_____

Will your duties for this position include duties that fall within the scope of your license?

**YES____ NO____

* If **YES**, you must provide a copy of your current license with this form to Human Resource to be credentialed **BEFORE** beginning **ANY** work at this VA Medical center.

PROCEDURES:
Research Personnel may be authorized to perform the following duties/procedures on a regular and ongoing basis.

Routine Duties Requested and Granted by PI	**PI Initial**
1. Screens patients to determine if study eligibility criteria are met by reviewing patient medical information or interviewing subjects.	_____
2. Develops recruitment methods to be utilized in the study.	_____
3. Performs venous puncture to obtain specific specimens required by study protocol **(requires demonstrated and documented competencies).	_____
4. Initiates submission of regulatory documents to IRB, VA R&D committees and sponsor(s).	_____

5. Prepares study initiation activities. _____

6. Provides education and instruction of study medication use, administration, storage, and side effects and notifies adverse drug reactions to study site. _____

7. Provides education regarding study activities to patient, relatives and Medical Center staff as necessary per protocol. _____

8. Maintains complete and accurate data collection in case report forms and source documents _____

9. Initiates and/or expedites requests for consulta-tion, special tests or studies following the Investigator's approval. _____

10. Obtains and organizes data such as test results, diaries/cards or other necessary information for the study. _____

11. Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects, research visits, documenting progress notes, initiating orders, consults, etc, per protocol, under supervision of PI. _____

12. Accesses patient medical information while maintaining patient confidentiality. _____

13. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent process per protocol, under supervision of PI. _____

14. Collects and handles various types of human specimens. _____

15. Performs study treatment and or assessment visits by tele-mental health per approved protocol. _____

MISCELLANEOUS DUTIES (if applicable):

Mr./Ms./Dr. _____ is authorized to perform the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____

2. _____

3. _____

PRINCIPAL INVESTIGATOR STATEMENT

Mr. / Ms. _____'s Scope of Practice was reviewed and discussed with him/her on the date of _____.

After reviewing his/her education, clinical competency, qualifications, research practice involving human subjects, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures. Both the Research Coordinator and I are familiar with all duties/procedures granted or not granted in this Scope of Research Practice. We agree to abide by the parameters of this Scope of Research Practice, all applicable hospital policies and regulations.

This Scope of Research Practice will be reviewed and amended as necessary to reflect changes in the research coordinator's duties/responsibilities, utilization guidelines and/or hospital policies.

_____	_____
Principal Investigator / Supervisor	Date
_____	_____
Alternate Supervisor (if applicable)	Date
_____	_____
Nurse Executive (Nurses Only)	Date
_____	_____
Research Personnel	Date

OFFICE USE ONLY

_____	_____
Research Compliance Officer	Date
_____	_____
ACOS/Research	Date

Revised February 13, 2015

Required VA Research Trainings for Employees and WOCs

1) ***VA Human Subjects and Good Clinical Practice Training*** (required biannually) located at https://www.citiprogram.org/
   - The CITI website allows people to self-enroll. It is very important when registering with the CITI website to affiliate with the Charleston VA.
   - During the enrollment process, the CITI site has new registrants answer a series of questions about the kind of research they'll be working on and it creates a lesson plan based on those responses.

2) All personnel involved in animal research must also complete the appropriate animal training modules, also located at https://www.citiprogram.org/

   Animal research personnel must complete the following:

   a) ***Working with the Charleston IACUC*** (required)
   b) ***Working with "species"*** (mice, rats, cats, etc.) in Research Settings (required)
   c) ***Post Procedure Care of Rodents*** (if applicable)
   d) ***Surgery*** (if applicable)

And

3) ***VA Privacy and Information Security Awareness and Rules of Behavior Training*** (required annually)**Course# 10176
   - located at https://www.tms.va.gov/learning/user/login.jsp
4) ***Privacy and HIPAA Training*** (required annually) **Course# 10203
   - located at https://www.tms.va.gov/learning/user/login.jsp
5) ***Ethics Training*** (required annually) **Course# 3812493
   - located at https://www.tms.va.gov/learning/user/login.jsp
6) ***Business Integrity Training*** (required annually) **Course# 7318
   - located at https://www.tms.va.gov/learning/user/login.jsp

If you do not have a TMS account, please use the provided instructions (User Job Aid: Create New non-VA User Record) to create a new one under the Research Service Line using John Midolo as your supervisor.

User Job Aid: Create New non-VA User Record

Purpose

The purpose of this job aid is to guide users through the step-by-step process of creating the Create New User tool in the VA TMS. In this job aid you will learn how to:

A. Create New User Record 9 Steps

B. Complete Required Training 6 Steps

Task A. Create New User Record

1 Step 1 Select "Check System." Install necessary updates. If necessary, adjust Pop-Up Blocker under the Tools tab.

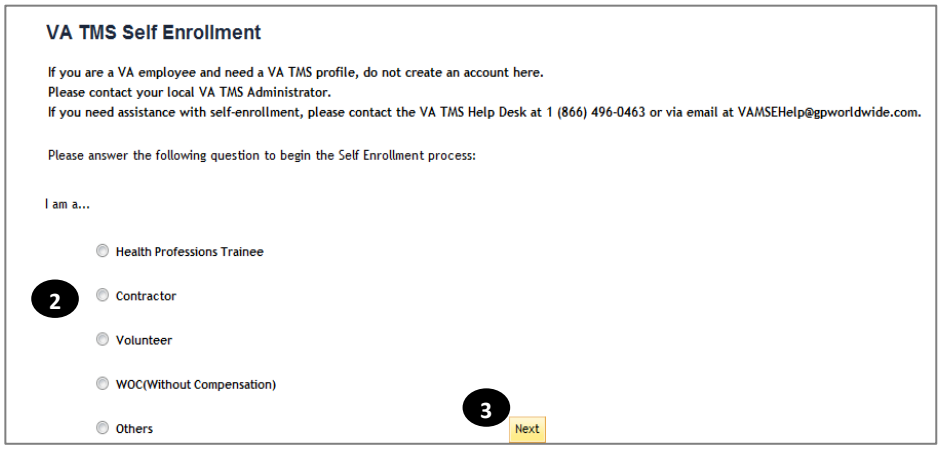
From the Login page, in the **brown** navigation bar click the **Create New User** link.

2 Step 2

In the **VA TMS Self Enrollment** page, select the appropriate employment type.

3 Step 3

Click **Next**.



4 Step 4

In **My Account Information** section, fill in all required fields as noted by the red asterisk, taking care to type accurately when entering your Social Security Number, e-mail address, and legal name; proceed to **Step 5**.

4a Step 4a

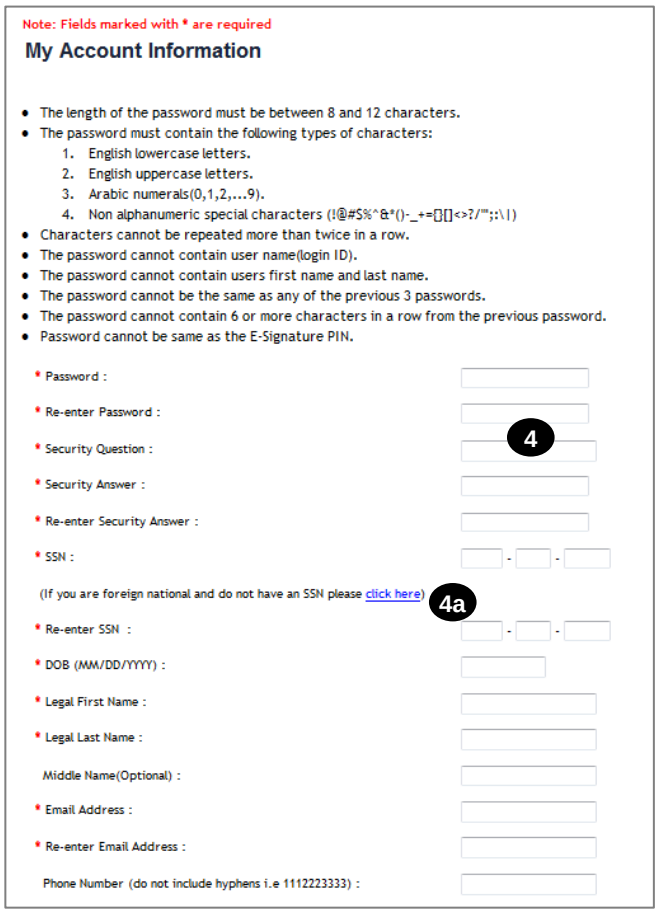
If you are a foreign national, click the **click here** link.

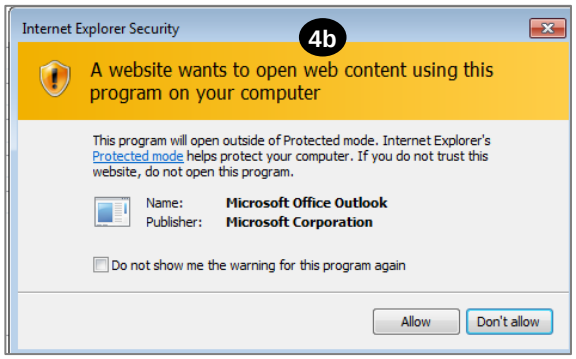
4b Step 4b

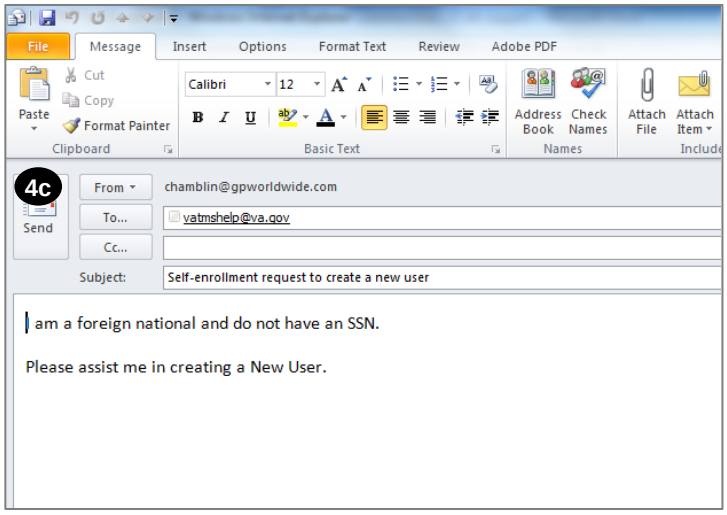
If there is a security pop-up click **Allow**.

4c Step 4c

In the email pop-up add any additional information to assist the Admin like your name and contact information and click **Send**.

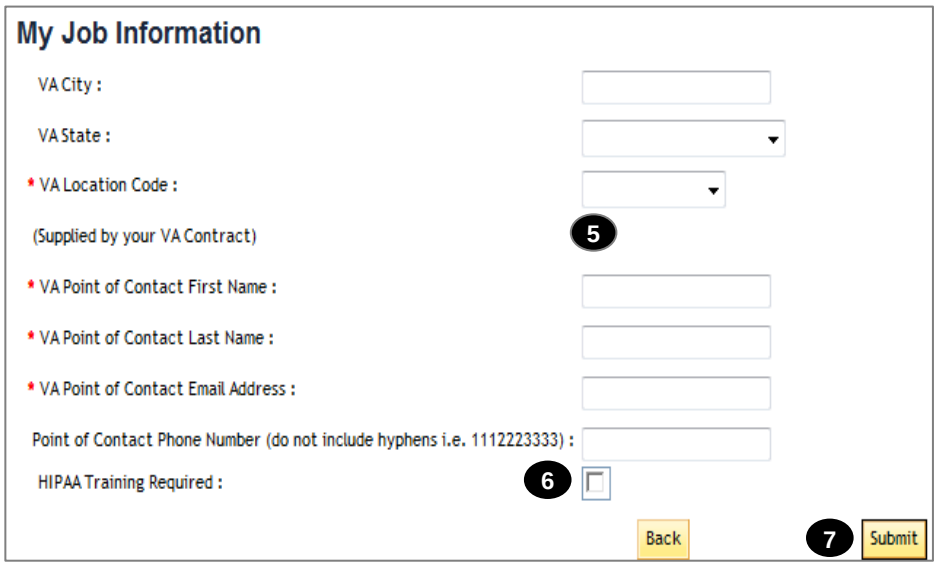






5 Step 5

In **My Job Information** section, fill in all required fields as noted by the red asterisk, entering the data provided by your VA point of contact where appropriate. ([1]See below).



6 Step 6

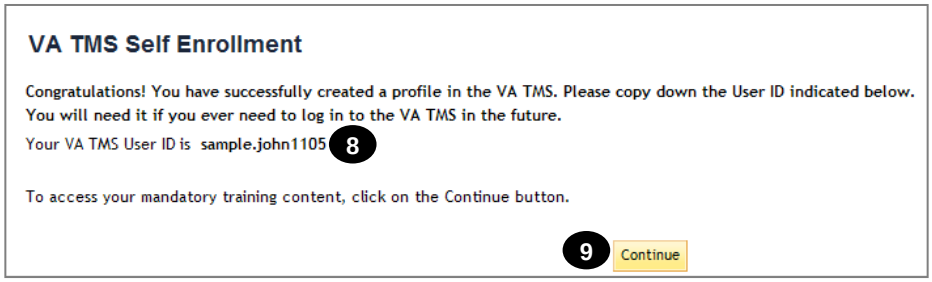
If you are required to take training on the Health Insurance Portability and Accountability Act (HIPPA), click the box. ***This applies to human subjects researchers. Please check this box***

7 Step 7

Click **Submit**.

8 Step 8

From the congratulations page, note your VA TMS USER ID for future use.



9 Step 9

Click **Continue**.

[1]VA City:	**Charleston**
VA State:	**South Carolina**
VA Location Code:	**CHA**
VA POC First Name:	**JOHN**
VA POC Last Name:	**MIDOLO**
VA POC Email Address:	John.Midolo@va.gov
VA POC Phone Number:	**8437896710**

Task B. Complete Required Training

1 Step 1

From the Home page, hover over item in your To Do List to display the pop-up menu.

2 Step 2

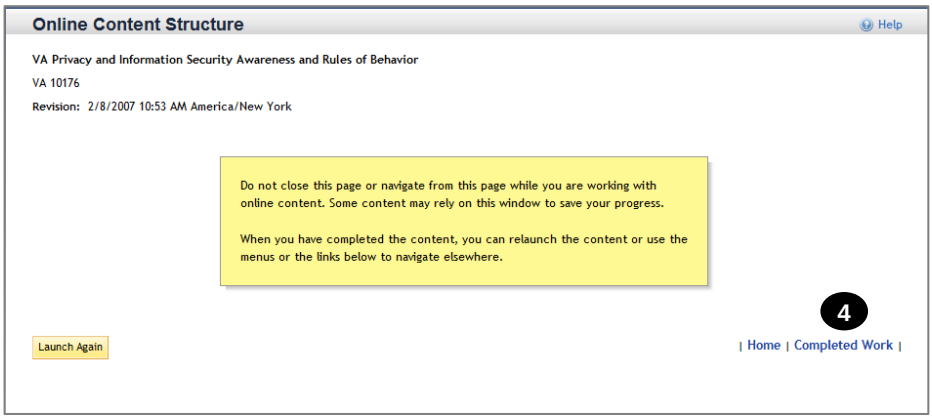
Click Go to Content.

3 Step 3

Complete training per instructions.

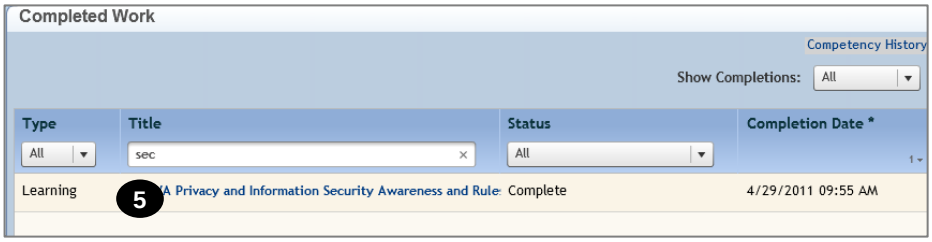
4 Step 4

On the Online Content Structure page, click the Completed Work link.



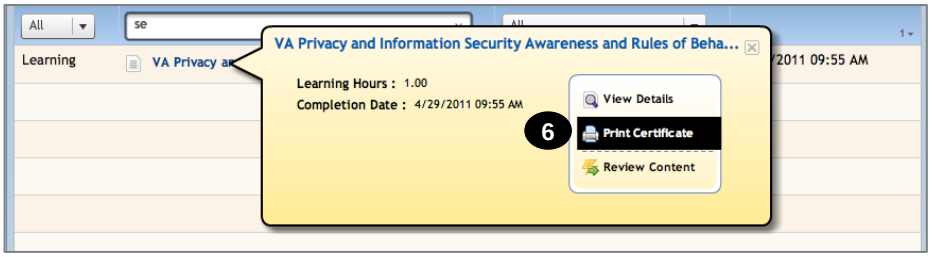
5 Step 5

From the Completed Work page, hover over the title of the completed training to display the pop-up menu.



6 Step 6

Click Print Certificate.



RALPH H. JOHNSON VA MEDICAL CENTER
CLINICAL STUDIES CENTER
EDUCATION VERIFICATION FORM

As part of the credentialing process it is necessary to verify educational credentials.
You must list all college/university degrees earned and all professional/technical/medical licensures/certifications **regardless of their relationship to the work you will be performing**. To assist us in completing this process, please provide the following information:

EMPLOYEE NAME	
UNIVERSITY/PROGRAM ATTENDED	
CITY / STATE / COUNTRY	
DEGREE/TRAINING	**DATE EDUCATION COMPLETED**
LICENSE/REGISTRATION STATE	
ISSUE DATE	**EXPIRATION DATE**
CERTIFICATION	**ISSUE/AWARD DATE – EXPIRATION DATE**
SOCIAL SECURITY NUMBER	**DATE OF BIRTH**
EMPLOYEE NAME	**EMPLOYEE SIGNATURE**

By signing this form, you authorize the Ralph H. Johnson VA Medical Center to contact the University, College or educational institution/program you attended to obtain verification of your educational credentials. Failure to disclose ALL requested information may result in disapproval or termination.

FOR OFFICE USE ONLY

DATE OF VERIFICATION	**DEGREE/CERTIFICATION VERIFIED**
SOURCE OF VERIFICATION	**VERIFICATION COMPLETED BY**

Revised: 06/18/09

RALPH H. JOHNSON VAMC IDENTIFICATION BADGE FORM

Section 1: Employee Information (COMPLETED BY EMPLOYEE)

Please fill out Section 1 completely. A valid driver's license or government issued photo identification card along with another form of government identification needs to be presented at the time of badge issuance.

Name: _____
Last *First* *Middle*

SSN: Date of Birth:

Address:

City, State, Zip:

Telephone #: Job Title: "This is for your WOC Position Only"

Race: Hair Color: Eye Color: Height: Weight:

Place of Birth (City/State):

Dept/Service Line: Research Service (151) Research Service (151)

_____
Signature of Sponsor Charles R. Holloman, 789-6703 *Date*

Section 2: Identification Verification (COMPLETED BY PIV PERSONNEL)

Photographic Identification Information 1

Exact name on Photo ID:

Document Type:

Issuing Authority:

Document Identification #:

Issuance Date:

Expiration Date:

Identification Information 2

Exact name on Photo ID:

Document Type:

Issuing Authority:

Document Identification #:

Issuance Date:

Expiration Date:

****TO BE SIGNED BY EMPLOYEE WHEN BADGE IS PICKED UP**

_____
Signature of Employee *Date*

Department of Veterans Affairs (VA) National Rules of Behavior

1. Background

a. Section 5723(b)(12) of title 38, United States Code, requires the Assistant Secretary for Information and Technology to establish "VA National Rules of Behavior for appropriate use and protection of the information which is used to support Department's missions and functions." The Office of Management and Budget (OMB) Circular A-130, Appendix III, paragraph 3(a(2)(a) requires that all Federal agencies promulgate rules of behavior that "clearly delineate responsibilities and expected behavior of all individuals with access" to the agencies' information and information systems, as well as state clearly the "consequences of behavior not consistent" with the rules of behavior. **The National Rules of Behavior that begin on page G-3, are required to be used throughout the VA**.

b. Congress and OMB require the promulgation of national rules of behavior for two reasons. First, Congress and OMB recognize that knowledgeable users are the foundation of a successful security program. Users must understand that taking personal responsibility for the security of their computer and the VA data that it contains or that may be accessed through it, as well as the security and protection of VA information in any form (e.g. digital, paper), are essential aspects of their job. Second, individuals must be held accountable for their use of VA information and information systems.

c. VA must achieve the Gold Standard in data security which requires that VA information and information system users protect VA information and information systems, especially the personal data of veterans, their family members, and employees. Users must maintain a heightened and constant awareness of their responsibilities regarding the protection of VA information. The Golden Rule with respect to this aspect of an employee's job is to treat the personal information of others the same as they would their own.

d. Since written guidance cannot cover every contingency, personnel are asked to go beyond the stated rules, using "due diligence" and highest ethical standards to guide their actions. Personnel must understand that these rules are based on Federal laws, regulations, and VA Directives.

2. Coverage

a. The attached VA National Rules of Behavior must be signed annually by all VA employees who are provided access to VA information or VA information systems. The term VA employees includes all individuals who are employees under title 5 or title 38, United States Code, as well as individuals whom the Department considers employees such as volunteers, without compensation employees, and students and other trainees. Directions for signing the rules of behavior by other individuals who have access to VA information or information systems, such as contractor employees, will be addressed in subsequent policy. VA employees must initial and date each page of the copy of the VA National Rules of Behavior; they must also provide the information requested on the last page, sign and date it.

b. The VA National Rules of Behavior address notice and consent issues identified by the Department of Justice and other sources. It also serves to clarify the roles of management

Initials: _____

Date: _____

and system administrators, and serves to provide notice of what is considered acceptable use of all VA information and information systems, VA sensitive information, and behavior of VA users.

c. The VA National Rules of Behavior use the phrase "VA sensitive information". This phrase is defined in VA Directive 6500, paragraph 5q. This definition covers all information as defined in 38 USC 5727(19), and in 38 USC 5727(23). The phrase "VA sensitive Information" as used in the attached VA National Rules of Behavior means:

> All Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and information that can be withheld under the Freedom of Information Act. Examples of VA sensitive information include the following: individually-identifiable medical, benefits, and personnel information, financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information, information that is confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege, and other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

d. The phrase "VA sensitive information" includes information entrusted to the Department.

3. Rules of Behavior

a. Immediately following this section is the VA approved National Rules of Behavior that all employees (as discussed in paragraph 2a of Appendix G) who are provided access to VA information and VA information systems are required to sign in order to obtain access to VA information and information systems.

Initials:_____
Date:_____

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.

Initials:_____

Date:_____

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.

Initials:_____

Date:_____

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

Initials:_____

Date:_____

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.

Initials:_____
Date:_____

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.

Initials:_____

Date:_____

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	
_____	_____
Office Phone or Cell	Position Title as a WOC

Initials:_____

Date:_____

RALPH H. JOHNSON DEPARTMENT OF
VETERANS AFFAIRS MEDICAL CENTER
CHARLESTON, SC

CENTER POLICY MEMORANDUM
NO. 05-13-29
January 29, 2013

MISTREATMENT OR ABUSE OF PATIENTS

I. PURPOSE. To inform all employees of the Department of Veterans Affairs policy with respect to mistreatment or abuse of patients. Also contained in this publication are responsibilities and procedures for reporting suspected or alleged acts of mistreatment or abuse.

II. POLICY.

A. It is a fundamental and strictly enforced policy of the Department of Veterans Affairs and of this Medical Center that no patient is to be mistreated or abused in any way, physically or verbally. In any case of suspected or alleged mistreatment or abuse, a prompt inquiry will be made to determine the facts, and where indicated, appropriate corrective action will be taken immediately.

B. The initial determination of reasonable evidence of mistreatment or abuse must, of necessity, rest in the sound judgment and discretion of the employee(s) witnessing or having knowledge of the incident. If any doubt exists as to whether a patient was mistreated or abused, the facts must be reported for a decision at a higher level of supervision.

C. Any employee who witnesses or otherwise has knowledge of mistreatment or abuse of a patient, and who does not report such information to supervisory personnel, is subject to disciplinary action.

III. DELEGATION OF AUTHORITY AND RESPONSIBILITIES.

A. Service Line Managers/Service Chiefs will review this memorandum with the employees in their services annually.

B. Supervisors should inform prospective employees of these policies and procedures at the time they report for duty. In addition, this subject should be discussed periodically in supervisory meetings.

C. Human Resources Management Service will present each new employee with a copy of Attachment A to this memorandum and will include this subject in the orientation of the employee.

D. Prior to entrance on duty, each employee will be required to sign a statement of understanding of actions in cases of abuse of patients by employees (Attachment A). The original signed statement will become a permanent part of the employee's electronic Official Personnel Folder (eOPF).

E. It is the responsibility of each employee to become familiar with the contents of this memorandum and to avoid any act which could possibly be considered mistreatment or abuse of patients. It is also each employee's responsibility to promptly report acts of mistreatment or patient abuse to the immediate supervisor.

IV. ACTION.

A. Reporting. Any evidence that a patient has been mistreated or abused in any way, physically or verbally, will be reported promptly both verbally and in writing to the immediate supervisor of the person observing the abuse or the next level supervisor if the immediate supervisor is unavailable. This report should take place on the day of occurrence of the incident, if at all possible, and describe the incident and who witnessed it. The written report should be made on VAF-119, Report of Contact. On the same day of the reporting of the incident, if at all possible, the supervisor of the area where the abuse is alleged to have occurred should conduct an initial inquiry into the incident. The supervisor will provide a report to the Office of Quality Management. Initial reports should contain, whenever feasible, written statements of witnesses and pertinent facts pertaining to the mistreatment or abuse. Based upon this information, a complete investigation will be requested by the Medical Center Director to fully explore all facets of the case.

B. Penalty. The penalty for abuse of a patient is removal. A lesser penalty (reprimand, admonishment, suspension, or demotion) may be imposed only when the act is of a minor nature and not a repeated offense. An act of minor nature may be teasing a patient; speaking harshly, rudely, or irritably to a patient; laughing at or ridiculing a patient; scolding a patient; indifference; etc. However, in certain cases any such act can be considered a major abuse subject to removal.

V. REFERENCES. VA Handbook 5021; 38 CFR Part 0.735-11(b), and 38 CFR 17.33(a) (1), (2).

VI. RESCISSION. Center Policy Memorandum No. 05-10-29 dated January 7, 2010.

CAROLYN L. ADAMS
Director

Attachment

RALPH H. JOHNSON DEPARTMENT OF
VETERANS AFFAIRS MEDICAL CENTER
CHARLESTON, SC

CENTER POLICY MEMORANDUM
NO. 05-13-29
ATTACHMENT A
January 29, 2013

Department of Veterans Affairs **MEMORANDUM**

Date:

From: Medical Center Director (00)

Subj: Actions in Cases of Abuse of Patients by Employees

To: All Employees

1. The following is quoted for your information from VA Handbook 5021 and is the Department of Veterans Affairs policy on patient abuse.

"It is a fundamental and closely guarded policy of the VHA that no patient is to be mistreated or abused in any way, physically or verbally, by any employee. Inquiry or investigation will be conducted in instances of alleged abuse or mistreatment. Appropriate disciplinary action must be taken promptly where indicated. In dealing administratively with this class of case as with other types of cases, charges of abuse or mistreatment must be sustained against an employee if the offense is reasonably established by the evidence. What is reasonable evidence of the fact of abuse or mistreatment must rest in the sound judgment and discretion of those charged with determining facts. (NOTE: A finding of abuse or mistreatment need not be predicated necessarily on proof of guilt beyond a reasonable doubt according to the rule prevailing in court determination of cases involving violation of penal statutes).

The administrative penalty action for patient abuse is removal. However, a lesser penalty (admonishment, reprimand, suspension, or demotion) may be imposed when mitigating or extenuating circumstances clearly warrant such lesser penalty or the nature of the abuse is minor. Abuse of a minor nature constitutes such acts as teasing a patient; speaking harshly, rudely, or irritably to a patient; laughing at or ridiculing a patient; scolding a patient; indifference; etc., though in certain instances such acts can be considered major abuse. An employee who witnesses any unkindness, rudeness, or violence of any kind towards a patient and who does not promptly report it to the proper authority is subject to disciplinary action."

2. After reading the above statement carefully, please return a signed copy to Human Resources Management Service to be filed in your Official Personnel Folder and retain one copy for your own records. If you have any questions, please contact Human Resources Management Service.

Carolyn L. Adams
Director

I have carefully read and understand the above statement.

_____ _____
SIGNATURE DATE

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

INTELLECTUAL PROPERTY

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides revised guidance and instruction regarding intellectual property (inventions) and the transfer of new scientific discoveries to benefit the public good (technology transfer).

2. SUMMARY OF MAJOR CHANGES: Corrects title of the agreement from Inter-institutional Agreement (IIA) to Cooperative Technology Administration Agreement (CTAA).

a. **Paragraph 2:** Describes dual appointment personnel, joint ownership, and Department of Veterans Affairs (VA) Without Compensation (WOC) Appointee Intellectual Program Agreement.

b. **Paragraph 4:** Adds additional definitions.

c. **Paragraph 6:** Corrects title from IIA to Cooperative Technology Administration Agreement (CTAA).

d. **Paragraph 12:** Notes requirements for State Department approval of foreign Cooperative Research and Development Agreement (CRADA)'s and that no inconsistencies exist between CTAA's and CRADA's.

3. RELATED DIRECTIVE: VHA Directive 1200.

4. RESPONSIBLE OFFICE: The Office of Research and Development (12) is responsible for the contents of this VHA Handbook.

5. RESCISSION: This VHA Handbook rescinds VHA Handbook 1200.18, dated May 17, 2001.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working date of November 2007.

Robert H. Roswell, M.D.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 11/05/2002
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/05/2002

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INTELLECTUAL PROPERTY HANDBOOK

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APPENDIX

A Contact Information A-1

INTELLECTUAL PROPERTY

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides guidance and instruction regarding intellectual property (inventions) and the transfer of new scientific discoveries to benefit the public good (technology transfer). ***NOTE:*** *The provisions of this Handbook apply to all research services within the Office of Research and Development (ORD) i.e., Medical Research Service (MRS), Rehabilitation Research and Development (RR&D), Health Services Research and Development Services (HSR&D), and the Cooperative Studies Program (CSP).*

2. BACKGROUND

a. Under Executive Order 10096, and Department of Commerce implementing regulations, Title 37 Code of Federal Regulations (CFR) Part 501, the Department of Veterans Affairs (VA) has the right to assert a right, title, and interest in and to all inventions made by any VA salaried employee under certain circumstances. Employees must have a duty to perform research for VA, which could consist of being assigned research duties and/or receiving any VA research intra-mural funding award. Executive Order 10096 also requires that the invention be made during working hours; with a contribution by VA of facilities, equipment, materials, funds, or information, or of time or services of other VA employees on official duty; or which bear a direct relation to, or are made in consequence of, the official duties of the inventor. In the case of a determination under 37 CFR 501, VA must promptly provide the employee with a signed and dated statement of its determination, a Determination of Rights Letter, and the reasons therefor, and a copy of 37 CFR Part 501. **Authority:** *37 CFR §501.7.*

b. VA recognizes that not all inventors may be full-time employees. Some may be part-time VA employees and part-time employees of another organization such as a university affiliate. Inventors may also be full-time employees of another organization granted access to VA resources (space, supplies, equipment, patients, etc.) after executing a VA-Without Compensation (WOC) Appointee Intellectual Property Agreement [see www.vard.org for specific instructions and form]. As a result of this unique relationship, an invention can be made while the inventor is acting as an employee of one or both organizations. It is important to realize that VA determines ownership rights only to the extent the invention was made in connection with the inventor's VA employment or with a substantial VA contribution. The Determination of Rights letter does not address any ownership rights another organization may have through the inventor. If another organization has a joint ownership interest, VA must contact and work with the joint owner to expedite the development of the invention. VA will also substantially share with the inventor and the facility any ensuing royalties.

3. SCOPE

a. The mission of the VA Technology Transfer Program (TTP) is to serve the American public by translating the results of worthy discoveries made by employees of VA into practice. This requires a program that educates inventors concerning their rights and obligations, rigorously evaluates all inventions, obtains patents, and assists in the commercialization of new products. It also requires consistent policies that govern the necessary relationships between

investigator (i.e., inventor), academic partners, local VA medical centers, industry, and the Department of Commerce. It requires close collaboration between ORD and the VA Office of General Counsel (OGC).

b. The TTP public mission requires aggressive dissemination of educational information to investigators and of products to the market. It is also necessary that VA assert an ownership interest whenever appropriate, so that discovery can be built upon. This ensures access to technologies by veterans.

NOTE: *TTP is committed to supporting the highest quality intramural research program. This means not only moving discovery from the laboratory to clinical practice in a timely manner, but also ensuring that inventors and their host VA medical centers receive optimal advice and support so that they may realize equitable compensation and recognition.*

4. DEFINITIONS

a. **Intellectual Property (Invention).** Intellectual property is any art, machine, manufacture, design, or composition of matter, or any variety of plant, which is or may be patentable under the patent laws of the United States (U.S.). **Authority:** *38 CFR 1.651.*

b. **Inventor.** The inventor is the individual responsible for the conception or reduction to practice of a device or process.

c. **Employee.** The term employee or Government employee means any officer or employee, civilian or military, of VA. For purposes of asserting VA ownership under Executive Order 10096, employee means an individual receiving salary from VA. **Authority:** *38 CFR 1.651.*

d. **Dual Appointment Personnel (DAP).** This term means a person who has an appointment, either salaried or without compensation with both VA and a university affiliate or other nonprofit organization.

e. **WOC Appointment.** This term refers to a situation where an individual has an appointment with VA, but is receiving no salary from VA, and whose invention cannot be claimed by VA under Executive Order 10096. ***NOTE:*** *This individual may be an employee of a university affiliate or other nonprofit organization.*

f. **VA-WOC Appointee Intellectual Property Agreement.** This term means a document signed by an individual who has a WOC appointment and is performing research within VA.

g. **Disclosure.** Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.

h. **Re-disclosure.** Re-disclosure is the formal written process of documenting all aspects relating to any improvement of a previously disclosed invention for the purpose of issuing a new determination on the improved invention.

i. **Premature Disclosure.** Premature disclosure is the presentation of too much data related to unpatented intellectual property in a public forum, e.g., scientific meeting, etc. ***NOTE:*** *Premature disclosure may result in the loss of patent filing rights.*

j. **Patent.** A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

k. **License.** A license is a written authority granted by the owner of a patent to another person, empowering the latter to make or use the patented article for a limited period or in a limited territory.

l. **Royalty.** A royalty is compensation for an invention.

m. **Copyright.** A copyright is a form of protection provided by Title 17 United States Code (U.S.C.) to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and other intellectual works, for a limited period of time. A copyright protects the form of expression, rather than ideas or the subject matter of the work. The copyright owner controls a number of exclusive divisible rights, the most fundamental one being the right to reproduce the work in copies.

5. INVENTION DISCLOSURE

a. In the case of an invention (to include improvement of an invention) or believed invention, the inventor must complete a VA certification page and prepare a statement for submission to the inventor's supervisor. These documents are available at the TTP website www.vard.org This statement consists of a:

(1) Narrative, detailed description providing sufficient information and detail for VA to ascertain ownership rights and to file the appropriate legal documentation required to protect the invention.

(2) A statement setting forth the circumstances attending the making of the invention. The statement must include:

(a) The full name and address of the inventor.

(b) The grade and title of the inventor's position.

(c) The inventor's employment status (full-time or part-time).

(d) The inventor's duties at the time the invention was made.

(e) The facts pertinent to a determination whether the invention bore a direct relation to, or was made in consequence of, such official duties.

(f) Whether there was, and if so the terms of, any special agreement or understanding with respect to the use or manufacture of the invention.

(g) The date of the invention, when and where it was conceived, constructed, and tested.

(h) Whether it was made entirely during working hours.

(i) Whether, and to what extent, there was a contribution by the Government of any of the following:

1. Facilities,

2. Equipment,

3. Materials or supplies,

4. Funds,

5. Information,

6. Time, or

7. Services of other Government employees on duty. **Authority:** *38 CFR §1.656.*

b. **Review and Submission.** The inventor's supervisor must review the employee inventor's statement. The file is then submitted via the local Research and Development (R&D) Office for review and approval and sent via courier to the Program Manager, R&D Technology Transfer Section (122TT) using the address listed under Contact Information. Once processed, TTP submits the disclosure to OGC. **Authority:** *38 CFR §1.656.*

c. **Potential Outcomes.** There are three possible outcomes to an invention disclosure. They are that the Government:

(1) Maintains right, title, and interest in, and to, any invention of a Government employee;

(2) Is entitled to a royalty free license with ownership remaining with the inventor; or

(3) Claims no interest or license; i.e., all rights remain with inventor.

d. **Appeals.** Any Government employee who is aggrieved by an agency determination may obtain a review of the determination by filing (within 30 days after receiving notice of such determination) two copies of an appeal with the Under Secretary of Commerce for Technology, c/o The Office of Federal Technology, Room 4837, U.S. Department of Commerce, Washington, DC 20230. On receipt of a copy of an appeal, the agency must furnish both the Under Secretary of Commerce for Technology and the inventor with a copy of a report containing the following information about the invention involved in the appeal:

(1) A copy of the agency's statement. **Authority:** *37 CFR §501.7.*

(2) A description of the invention in sufficient detail to identify the invention and show its relationship to the employee's duties and work assignments.

(3) The name of the employee and employment status, including a statement of official duties and responsibilities at the time the invention was made.

(4) A detailed statement of the points of dispute or controversy, to include copies of any statements or written arguments filed with the agency, and of any other relevant evidence that the agency considered in making its determination. **Authority:** *37 CFR. §501.8.*

6. COOPERATIVE TECHNOLOGY ADMINISTRATION AGREEMENTS (CTAA)

a. Retention of ownership and protection of intellectual property developed by VA investigators are key issues of importance. It is also important to acknowledge cases where co-ownership issues exist with VA academic affiliates. To address this issue, a model CTAA was developed in collaboration with the Office of General Counsel (OGC). This legal agreement outlines relevant definitions, terms, and conditions for handling intellectual property between both organizations.

b. Using the CTAA allows VA a co-ownership interest while providing the academic affiliate unimpeded access and authority to patent and market the intellectual property in question. This makes the invention attractive to manufacturers ensuring that if they develop the product for the marketplace, they will have exclusive rights to produce and market the invention. The overall benefit to the Government and the taxpayers is that an invention resulting from Federally-funded research will be protected by a patent.

c. Successful patents licensed to manufacturers provide a royalty stream. As a result, VA inventors benefit from royalties for their personal use, as well as a return of royalties to their research laboratories and facility. The American taxpayer gains by the return of funds to the laboratories to further medical research. Using CTAA's provides a win-win situation for VA and academic affiliates, while maintaining, strengthening, and/or expanding existing partnerships to the mutual benefit of both organizations. ***NOTE:*** *CTAAs are used with academic affiliates whenever possible.*

d. CTAAs are developed by the TTP staff, OGC, and the academic affiliate. For additional information, sample CTAAs are available at the TTP internet web site under the Technology Transfer link (see App. A for web site address).

7. PATENTS

a. Once intellectual property has been disclosed and reviewed by OGC and a determination has been made to retain ownership of an invention, the VA patent process begins. Under 35 U.S.C. §207, VA is authorized to apply for, obtain and maintain patents or other forms of protection in the U.S. and in foreign countries on inventions in which VA owns a right, title or interest.

NOTE: *Any invention owned by the Government under the criteria set forth in 37 CFR §501.6 needs to be protected by an application for a domestic patent and other necessary documents executed by the employee inventor prepared by or through the General Counsel, Deputy*

General Counsel, or the Assistant General Counsel for Professional Staff Group IV.
Authority: *38 CFR §1.654.*

b. VA may elect to use outside counsel (or other means to be identified), if it is determined appropriate. All VA-owned inventions not covered by CTAAs must receive centralized patenting support arranged and coordinated through the TTP. This support includes handling patent applications, provisional patents, patent filings, follow-up requests for information concerning pending patent applications, international filings where applicable, and other necessary actions. ***NOTE:*** *These services are provided at no cost to the facility or investigator.*

c. If it is determined that the employee inventor is entitled to full ownership under 37 CFR §501.6, subject to a non-exclusive, irrevocable, royalty-free license in the Government, it is the duty of the employee inventor to notify OGC of the status of the patent application, including the patent application number so that VA may protect interests reserved to the Government. **Authority:** *38 CFR §1.655.*

8. COPYRIGHT

a. Title 17 U.S.C. Section 105, the U.S. Copyright Act, provides that copyright protection is not available for any "work of the United States Government" defined under the Copyright Act as a work prepared by an U.S. Government employee as part of that person's official duties (17 U.S.C. § 101). Consequently, works such as instructional materials prepared exclusively by VA employees as part of their official duties are not copyrightable, but are placed into the public domain. Section 105, however, permits the U.S. Government to receive and hold copyrights transferred to it by assignment, bequest, or otherwise.

b. Works prepared for the U.S. Government under a U.S. Government contract or grant may be copyrighted by the contractor or grantee unless the U.S. Government provides in the contract or grant that copyright is prohibited or, in a written instrument signed by the parties, that the U.S. Government owns all of the rights comprised in the copyright. It is U.S. Government policy to:

(1) Recognize that the owner of a copyright has a legally enforceable property right in the copyrighted work, and

(2) Obtain or procure a proper license or permission to use copyrighted works.

9. MARKETING

a. A critical component of any successful intellectual property program involves marketing new inventions or technologies to ensure timely production and introduction into the marketplace. All VA-owned inventions not covered by CTAAs receive centralized marketing support arranged and coordinated through VHA Central Office. ***NOTE:*** *Currently, contractor expertise is available in the areas of initial technology screening and comprehensive technology assessment.*

b. The comprehensive technology assessment provides:

(1) Industry feedback,

(2) Identification of potential licensees,

(3) Comparison of competing technologies,

(4) Evaluation of trends and market size, and

(5) Identification of alternative applications.

c. In-house or contractor service is provided to identify market potential and compatible industry partners interested in commercialization of new products.

NOTE: *A Technology Transfer Advisory Group consisting of experts familiar with, and experienced in, the field of intellectual property and commercialization of new products assists in guidance, oversight, and monitoring of VA technology transfer operations.*

10. LICENSE

a. All VA owned inventions not covered by CTAAs receive centralized support arranged and coordinated through VHA Central Office in negotiating licenses with commercial entities for intellectual property owned by VA. These efforts ensure that industry partners identified through marketing efforts receive a license to manufacture and sell the intellectual property in question. These services must be provided at no cost to the facility or investigator.

b. Under 35 U.S.C. §207, VA is authorized to grant non-exclusive, exclusive, or partially exclusive licenses under federally owned inventions. Prior to granting a license application, VA must ensure that the criteria in 35 U.S.C. §209 have been satisfied.

c. License applications received from interested parties requesting the use of intellectual property owned by VA are reviewed to determine if specific legal requirements are met. The license application must satisfy the requirements and criteria set forth in 37 CFR Part 404.

11. ROYALTIES

a. Royalty income to VA is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the program's effectiveness, and ensures compliance with applicable laws; e.g., the current Federal royalty income cap of $150,000 per year per employee. ***NOTE:*** *Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.*

b. Royalty payments must be made in U.S. dollars only by check or bank draft drawn on a U.S. bank payable to Department of Veterans Affairs (royalty) and sent to: Department of Veterans Affairs, Technology Transfer Program (122TT), 810 Vermont Avenue, NW, Washington, DC 20420. Under this policy, 85 percent of royalty funds received is returned to the local facility to support ongoing research activities. ***NOTE:*** *The most recent royalty policy is available at the TTP internet web site under the Technology Transfer link.*

12. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

A CRADA is an agreement between VA and one or more non-Federal parties under which VA "laboratory directors" (defined herein as medical center Directors) may accept, retain, and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties in order to conduct R&D in a particular project. This may include the further development of a VA-owned invention and may be entered into in cooperation with a license agreement. ***NOTE:*** *Proposed CRADA's can not be inconsistent with CTAA terms.*

a. In exchange for what VA receives from a collaborating party, VA may provide personnel, services, facilities, equipment, or other resources, but not funds toward the conduct of specified R&D efforts consistent with VA's mission. The CRADA may provide for potential licenses or, in exceptional circumstances, assignments, or options, for reasonable compensation (when appropriate) to collaborating parties for any inventions made by a Federal employee under such agreements. However, a non-exclusive, non-transferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world, by or on behalf of the Government, must be retained. In such cases where it is determined to grant any of the rights in advance, those rights must be granted directly to the collaborating party.

b. CRADAs are negotiated by the VA medical center and regional counsel attorneys. Following review and approval by OGC, they are returned to the medical center for execution. CRADAs dealing with foreign countries require advance State Department approval prior to execution. This could add considerable time to the overall approval process. The most recent information regarding CRADAs, including sample agreements, is available at the TTP internet web site under the Technology Transfer link.

13. INQUIRIES

Information regarding points of contact for issues related to intellectual property is contained in Appendix A.

CONTACT INFORMATION

1. Inquiries regarding intellectual property need to be directed to:

   a. Program Manager
   Technology Transfer Program
   Department of Veterans Affairs (122TT)
   810 Vermont Avenue, NW
   Washington, DC 20420
   (410) 962-1800 x267

   or

   b. Director (or Deputy Director)
   Technology Transfer Program
   Department of Veterans Affairs (122TT)
   810 Vermont Avenue, NW
   Washington, DC 20420
   (202) 408-3670

2. Additional information can be obtained at http://www.vard.org by clicking Department of Veterans Affairs Technology Transfer Program link.

VA-WOC APPOINTEE INTELLECTUAL PROPERTY AGREEMENT

This agreement is made between _____ and the Department of Veterans Affairs (VA) in consideration of my without compensation (WOC) appointment by the VA Medical Center at Charleston, South Carolina, (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 VAMC for the purpose of performing research projects, evaluated and approved by the VA 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 (Handbook) [available at www.vard.org], 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 Medical University of South Carolina, 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.

_____	_____
Date	Signature
_____	_____
Date	ACOS for Research

VA-WOC APPOINTEE INTELLECTUAL PROPERTY AGREEMENT

This agreement is made between _____ and the Department of Veterans Affairs (VA) in consideration of my without compensation (WOC) appointment by the VA Medical Center at Charleston, South Carolina, (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 VAMC for the purpose of performing research projects, evaluated and approved by the VA 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 (Handbook) [available at www.vard.org], 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 Charleston Research Institute (CRI), 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.

_____	_____
Date	Signature
_____	_____
Date	ACOS for Research