VA Ann Arbor Healthcare System
(VAAAHS) Research Service (151)

NEW Without Compensation Applicant (WOC)

Update - June 2016

Welcome to the Veterans Affairs Ann Arbor Healthcare System (VAAAHS) Research Service!

Conducting research in the VAAAHS presents unique opportunities and challenges. The VAAAHS has a specific mission and the Research Service supports this mission.

The VAAAHS mission is to honor America's Veterans by providing exceptional healthcare that improves their health and well-being.

This mission folds into the overall Veterans Administration (VA) mission to fulfill President Lincoln's promise 'To care for him who shall have borne the battle, and for his widow, and his orphan' by serving and honoring the men and women who are America's Veterans.

The mission of the Research and Development (R&D) program (or Research Service) is to discover knowledge and create innovations that advance health care for ***Veterans*** and the Nation.

The values guiding all R&D efforts include: scientific excellence; the ethical conduct of research; protection of human subjects; the welfare of laboratory animals; the safety of those involved in the research program; and the security of both our research laboratories, other research resources, and **research data** (VHA Directive 1200, 13 May 016).

The Ann Arbor Research Business/Administrative Office provides the following support services: administrative support for the R&D Committee, Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Subcommittee on Research Safety (SRS); administrative and personnel support for committee review and record-keeping functions; space sufficient to provide privacy for conducting sensitive duties related to biosafety and the protection of human and animal subjects involved in research (VHA Directive 1200, 13 May 2016).

In order to particpate in the unique reasearch programs of the VA and advance the health of our nation's ***Veterans***, you must be appointed as a paid employee, without compensation employee (WOC), or appointed or detailed through the authority of the Intergovernmental Personnel Agreement (IPA) (VHA Directive 1200, 13 May 2016).

To make this happen, the Research Service is required to collect and maintain certain personal, professional and education/training information. As a WOC employee, you will be required to renew your status annually until such time as you leave service. The following packet was designed to capture all required and pertinent information in one location.

WOC Application Instructions
June 2016

This packet is divided into five sections. All forms are fillable PDFs. Digital signatures are acceptable, except where noted otherwise.

1. Administrative -- Forms required for all applicants.
2. Standard Training -- Training required for all applicants.
3. Laboratory Workers -- Training/forms required for all applicants working in laboratories of any kind.
4. Human Research -- Training/forms required for all applicants working in human research studies, to include data analysis, human subject contact, human tissue contact, human fluids contact.
5. Animal Research -- Training/forms required for all applicants working on a study that is linked to animal research.

All applicants must work with their supervisor, study coordinator and principal investigator to complete the forms/training in this packet **PRIOR** to making an appointment to process through the Research Service Administrative Office.

If you will be working at the Health Services Research & Development (HSR&D)/Center for Clinical Management Research (CCMR) or in the Serious Mental Illness Treatment Resource and Evaluation Center (SMITREC), you **MUST** contact Art Davidge at 734-845-3606 prior to your in-processing appointment in the Research Service.

COMPUTER ACCOUNTS -- Please confirm with your supervisor, study coordinator and/or principal investigator whether you will need access to VA programs/software and/or require a VA computer account.

Computer accounts cannot be requested until fingerprinting and a background check are completed. Please plan accordingly when hiring your WOC employees with a target date in mind.

Once you have completed all required forms and training, contact Christina Wayne via email (christina.wayne@va.gov) to schedule your processing appointment. Please schedule this appointment at least three days before your projected start date and allow **AT LEAST** one hour for processing in the Research Service, plus time at Human Resources.

Items to bring to your appointment:

1. Printed copies of ALL required forms (single-sided).
2. Printed copies of ALL required training certificates (single-sided).
3. Two forms of identification (see the I-9 Proofing Criteria).
4. One copy of your CV/resume (single-sided).

ALL PAGES MUST BE SUBMITTED AS SINGLE-SIDED

Administrative Forms

OF 306, Declaration for Federal Employment

(REQUIRED)

PLEASE CLICK ON THIS WEB-LINK TO ACCESS OF306

http://www.opm.gov/Forms/pdf_fill/OF306.pdf

ADDITIONAL INSTRUCTIONS

1. **Fill in or check all boxes through question 15.**
2. **Sign 17a. Applicant's Signature in ink (digital signature not accepted).**
3. **DO NOT fill in or sign any other blocks, unless you answered yes to any questions that require further explanation.**

APPENDIX B – IDENTITY (I-9) PROOFING DOCUMENTATION CRITERIA

1. The following criteria must be met by all VA employees, contractors, and affiliates (WOCs) prior to being issued a PIV card or Non-PIV Card.

2. FIPS 201-1, Section 2.2 states the applicant shall be required to provide two original forms of identity source documents. The identity source documents are taken from the list of acceptable documents included in *Form I-9, OMB No. 1615-0407, Employment Eligibility Verification*, dated August 7, 2009. At least one document shall be a valid State or Federal government-issued picture identification (ID).

3. Identity Document Criteria

a. The Registrar must examine each identity source document provided by the Applicant.

b. All identity source documents must be unexpired.

c. Any document that appears invalid (e.g., absence of security hologram or other known security features on a State issued driver's license; absence of security features on a birth certificate or passport; smeared ink; missing information; etc.) is to be rejected by the Registrar and reported to the Office of Security and Law Enforcement (OSLE) for review.

d. Handwritten or photocopied documents are not acceptable.

4. Acceptable Identity Documents. Two forms of identification are required from Table 1: Acceptable Identity Documents. The following combinations are accepted:

a. Two forms of identification from Column A (Government Issued Photo ID);

b. One form of identification from Column A and one form from Column B (Non-Picture ID or Acceptable Picture ID not issued by Federal or State Government); or

c. For persons under the age of 18 who are unable to present a document from Column A, the following documents are acceptable:

(1) School record or report card or

(2) Clinic, doctor, or hospital record.

5. Applicant Names

a. The name of the Applicant in the card request must match the name exactly as printed on at least one of the identity source documents. The names on the identity source documents must match using the examples in Table 2: Acceptable Name Mismatches and Table 3: Not Acceptable Name Mismatches.

b. Applicants with multiple last names may use the guidance for middle names in Table 2: Acceptable Name Mismatches.

c. An ID issued before a legal name change (e.g., birth certificate or driver's license) can be presented as one form of ID if a legal document (e.g., marriage certificate/license or a court order) is also presented linking the previous name to the current legal name. The linking document has to display both the former and current legal names. Both documents must be valid and not expired. For example, a married woman may use both a certified copy of her birth certificate displaying her maiden name and a driver's license displaying her married name as the 2 forms of ID compliant with PIV Guidelines as long as she provides a marriage license displaying both her maiden name and married name.

Table 1. Acceptable Identity Documents

<table>
<tr><th>COLUMN A
Government Issued Photo ID</th><th>COLUMN B
Non-Picture ID and or Acceptable Picture ID not issued by Federal or State Government</th></tr>
<tr><td>• U.S. Passport or U.S. Passport Card
• Permanent Resident Card or Alien Registration Receipt Card (Form I-551)
• Foreign passport that contains a temporary I-551 stamp
• Employment Authorization Document that contains a photograph (Form I-766)
• Foreign passport with Form I-94 or Form I-94A
• Passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A
• Driver's license or State issued ID card
• Federal, state, or local government issued ID card
• School ID with photograph
• U.S. Military card
• Military dependent's ID card
• U.S. Coast Guard Merchant Mariner Card</td><td rowspan="3">• Social Security Card
• Original or certified Birth Certificate
• Certification of Birth Abroad Issued by the Department of State (Form FS-545)
• Certification of Report of Birth issued by the Department of State (Form DS-1350)
• Voter's Registration Card
• Native American Tribal Document
• U.S. Citizen ID Card (Form I-197)
• Identification Card for Use of Resident Citizen in the United States (Form I-179)
• Employment Authorization document issued by the Department of Homeland Security
• Canadian Driver's License</td></tr>
<tr><th>For persons under age 18 who are unable to present a document listed above:</th></tr>
<tr><td>• School record or report card
• Clinic, doctor, or hospital record</td></tr>
</table>

Table 2. Acceptable Name Mismatches

Name	Acceptable Mismatches	
	First Name Source Shows	Second Name Source Shows
First	Single first name Example: “Mary” (with “L.” given as middle initial)	First name as two words Example: “Mary Lou”
Middle	Single letter as middle initial Example: “L.”	Middle name spelled out, first letter of the name matches the single letter Example: “Lawrence”
	Compressed middle name Example: “Heewan”	Properly-formed expansion of middle name Example: Hee-Wan
Last	Last name given in hyphenated form Example: “Smith-Jones”	Last name given in non-hyphenated form Example: “Smith Jones”

Table 3. Not Acceptable Name Mismatches

Not Acceptable Mismatches	First Name Source Shows	Second Name Source Shows
Apparent typo or transposition of letters in the name	“John” “Smyth”	“John” “Smith”
Mismatch between given name and an alias or nickname	“Jim”	“James”
First and middle names swapped	“Eldon S. Smith”	“Scott Smith”
Mismatch of suffix	“Tom Smith Jr.”	“Tom Smith”

SF – 87 WORK SHEET

PLEASE PRINT LEGIBLY

Name: **Enter N/A as appropriate**	**FIRST:** **Full Middle Name:** **or** **Middle Initial Only:** **or No Middle Name:** **LAST:**
Other Names Used: Maiden Name, Aliases, AKA, Nicknames or N/A	
Social Security Number:	
Date of Birth:	
Race / Ethnicity:	Asian/Pacific Islander
Gender:	
Height:	**Feet:** 7 **Inches:** 4
Weight:	**Pounds**
Place of Birth: **Enter N/A as appropriate**	**City/State:** **OR** **Province/Country:**
Hair Color:	Brown
Eye Color:	Brown
Current Address & Home Phone:	**Street Address:** **City:** **State:** **Zip:** **Home Phone:**
Citizenship:	
Job Title or Affiliation:	**VA Employee Title:** Research Assistant **Supervisor:** **PIV Issue?** Yes **VA computer access?** Yes **Fingerprinted at this VA facility within last 6 months?** Yes

Forms To Be Filled Out with Principal Investigator and/or Supervisor

The following forms are meant to be filled out by the PI and/or Supervisor with the WOC employee present. This ensures the employee understands their responsibilities and duties and knows which projects they are assigned to.

1. Principal Investigator Information
2. Research Credentialing
3. Scope of Practice

When referencing any VA study on forms, please use the VA title and VA (#XXXX) number.

Principal Investigator Information

*The principal investigator must **complete** and **sign** this form.*
WOC applicants will not finish processing without this completed form.

Employee Name *(Last, First, MI)*

Describe applicant duties:

Work Location

Room Building

☐ **Lab employees:** *Lab safety orientation is required. Employee must bring a completed **Research Safety Checklist** when processing.*

Will this person work with

☐ **Animals**: If working with **animals**, applicants must complete all appropriate training and Occupational Health & Safety Survey and submit all certificates during processing.

- ☐ *Working with the VA IACUC* - Everyone complete.
- ☐ *Working with (species) in Research Settings* - List species Rats
- ☐ *Post Procedure care of Mice and Rats* - If survival surgery is performed on protocols listed.

☐ **Humans:** If working with **identifiable data** and/or **specimens**, **interacting with human subjects** and/or assigned to a **human** study, all research employees on VA projects must complete and provide certificates for *Protections of Human Research Subjects and Good Clinical Practice*.

List specific project(s) with VA#

a.

b.

c.

Access Needed

☐ VA Computer Account ☐ Research Building ☐ Remote Access/VPN

☐ CPRS -- Read/write authorization? Read

Investigator Signature	**Date**

Requirement for Credentialing and
Scope of Practice or Functional Statement
for All Personnel Conducting VA Research Activities

Department of Veterans Affairs (VA) Veterans Health Administration (VHA) Directives 1200, *Veterans Health Administration Research and Development Program*, 2012-030, *Credentialing of Health Care Professionals*, and VHA Handbook 1100.19, *Credentialing and Privileging*, outline requirements for credentialing, privileging, and scopes of practice and funcational statements for VHA personnel conducting VA research activities. Research personnel consist of all personnel appointed officially as paid employees, without compensation employees (WOC), or either appointed or detailed through the authority of the Intergovernmental Personnel Agreement (IPA).

The Associate Chief of Staff for Research and Development (ACOS/R&D) or the Administrative Officer for R&D (AO/R&D) is responsible for the following in the VAAAHS Research Service.

1. Ensuring all individuals are appropriately credentialed and privileged (if applicable) before appointment. In any case, a Research Scope of Practice Statement or Functional Statement must be defined for all individuals conducting VA research, including individuals who do not function as health care providers.
2. Ensuring the ethical conduct of research and the adequate protection of human participants in research.
3. Ensuring that all VA employees involved in the R&D program comply with ethics laws, regulations and principles.

The Scope of Practice Statement or Functional Statement must be consistent with the position to which the individual is appointed.

1. Statement must define the duties of the individual.
2. Statement must **NOT** include any duties or procedures for which the individual is not qualified.
3. Clinical privileges may be used in lieu of a Scope of Practice Statement if the individual holds privileges at the facility and the research responsibilities and duties match the clinical privileges.
4. Additional duties and responsibilities should be included in the Statement.
5. A Functional Statement may used in lieu of the Scope of Practice Statement if applicable to the position the individual holds.
6. Contractor duties, credentialing, privileging and background investigation requirements must be clearly defined in the contract.

All staff that, by virture of their education and training, are eligible to obtain licensure, registration or certification are required to be credentialed through VetPro, even if they do not hold an active license, registration or certification at the time of appointment.

Staff that **MUST** be credentialed through VetPro include

1. All health care professionals who claim licensure, certification, or registrations as applicable to their position within the VHA.
2. All research staff that hold a degree that may make them eligible for licensure, certification or registration. Such persons include, but are not limited to, nurses, physicians, foreign medical graduates, clinical psychologists and pharmacists that do not have a current active license.
3. All research staff, including research administrative personnel, who, by the nature of their position, have the potential to assume patient care-related duties or oversee the quality or safety of patient care delivered.

Definitions

Associate Chief of Staff for Research and Development (ACOS for R&D) (VHAD 1200), 070909 - Individual responsible for the day-to-day management of the research program at facilities with large, active programs.

Clinical Privileging (VHAD 1100.19, 101512) - The process by which a practitioner, licensed for independent practice (i.e., without supervision, direction, required sponsor, preceptor, mandatory collaboration, etc.), is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experiences, health status, education, training, and licensure. Clinical priveleges must be facility-specific, practioner-specific, and within available resources. NOTE: There may be practioners who by the nature of their positions, are not involved in patient care (i.e., researchers, administrative physicians, or VHA Central Office staff). These health care professionals must be credentialed, but may not need to be privileged.

Credentialing (VHAD 2012-030, 101112) - The systematic process of screening and evaluating qualifications and other credentials, including licensure, registration, certification, required education, relevant training and experience, and current competence. ***NOTE:*** *Practitioners who are not directly involved in patient care (i.e., researchers or administrative personnel), but by the nature of their position, have the potential to assume patient care-related duties, or oversee the quality or safety of the patient care delivered, must be credentialed.*

Licensure (VHAD 2012-030, 101112) - The official or legal permission to practice in an occupation, as evidenced by documentation issued by a state, Territory, Commonwealth, or the District of Columbia in the form of a license or registration. ***NOTE:*** *See attachment B for occupations that require or may claim licensure, registration, or certification. See Attachment C for occupations covered by Title 38 United States Code (U.S.C.) Section 7402 (F).*

Registration or Certification (VHAD 2012-030, 101112) - The official confirmation by a professional organization that one has fulfilled the requirements or met a standard or skill to practice the profession.

Research Scope of Practice Statement (VHAD 1200, 070909) - A written document that defines the parameters and functions of an employee's duties and responsibilities. These duties and responsibilities must be consistent with the occupational category under which they are hired (appointed by the Human Resources Manager to the position), allowed by the license, registration, or certification they hold, consistent with their qualifications (education and training), and be agreed upon by the person's **immediate supervisor** and the **ACOS/ R&D**. When the employee is working on specific research protocols, the **Primary Investigator** for each protocol must also agree with the Scope of Practice Statement.

VetPro (VHAD 2012-030, 101112) - Internet enabled data bank for the credentialing of VHA personnel that facilitates completion of a uniform, accurate, complete credentials file.

Research Credentialing Verification

Name (First Middle Last)	Email address
Principal Investigator	Work Phone
SSN	Date of Birth

Home Address: _____

1. Do you hold a degree that **may** make you eligible for licensure, registration or certification?
   No

2. If yes, list specific degrees that apply (MBBS, MD, RN, MSW, RRT, PhD).

3. Please list all current or past licensures, registrations, or certifications (no matter the State or specialty these were held in).

4. Is an MD or PhD required for your position? No
5. Will you be a provider noted on patient records? No
6. Will you enter information into patient records? No
7. Are you credentialed in VetPro? No
8. Applicant is Female
9. Citizenship US
10. Work Status WOC

Employee Signature _____ Date

PI Signature _____ Date

VA HEALTH CARE Defining EXCELLENCE in the 21st Century
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Scope of Practice for Research Personnel

NAME OF RESEARCH PERSONNEL	EMAIL ADDRESS
PRIMARY SUPERVISOR *(conducts the employee's annual evaluation and initiates this form)*	**ROLE IN RESEARCH** *(Investigator, Research Staff, Statistician, Consultant, Etc…)*

Please indicate type of Employee:

☐ Study Team Member – VA Employee

☐ Study Team Member – IPA or WOC Employee

1. RESEARCH TEAM MEMBERS: The Scope of Practice is specific to the duties and responsibilities of Research Personnel (Employee or WOC) as an agent of the listed Supervisor. As such he/she is specifically authorized to conduct research with the responsibilities outlined below. Only one Research Scope of Practice is required for each Research Staff Member. When Research personnel are involved in multiple studies, this scope of practice should encompass all of the duties that the individual is authorized to perform. All Principal Investigators for whom the staff member will be working (who are not the supervisor), should also review the Scope of Practice Statement to ensure that the duties authorized match those that will be performed as part of the research. Local training may be required to perform some of the duties authorized to conduct a study.

2. PRINCIPAL INVESTIGATORS: A Scope of Practice must be completed for Principal Investigators to delineate their Research duties outside of the Credentialing and Clinical Privileges granted by the Medical Center. This includes all duties performed in addition to the PI oversight responsibility.

3. PROCEDURES: The supervisor(s) must complete this Scope of Practice granting duties/procedures the personnel may be authorized to perform on a regular and ongoing basis. Please check and complete the applicable Sections I and II. Section III is required for all Scopes of Practice.

☐ **SECTION I** is completed for Human Subject research activities.

☐ **SECTION II** is completed for Bench and/or Animal research activities.

SECTION III requires signatures of the Research Personnel and PI/VA Supervisor and date. If the individual works for more than one PI, that PI should also review this document.

SECTION IV Documentation of Annual Review will be required annually at the time of Continuation Review.

SECTION I HUMAN SUBJECT RESEARCH

Routine Duties	YES	NO
1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	☐	☐
2. Develops recruitment methods to be utilized in the study.	☐	☐
3. Performs venipuncture to obtain specific specimens required by study protocol (requires demonstrated and documented competencies).	☐	☐
4. Initiates submission of regulatory documents to VAAAHS VA IRB, VA R&D committee, sponsor and other regulatory agencies.	☐	☐
5. Involved in study medication use, administration, storage, side effects and notification of adverse drug reactions to study site.	☐	☐
6. Provides education to patient, relatives and Medical Center staff regarding study activities.	☐	☐
7. Maintains complete and accurate data collection in case report forms and source documents.	☐	☐
8. Initiates and/or expedites requests for consultation, special tests or studies following the Investigator's approval.	☐	☐
9. Demonstrates proficiency with VISTA/CPRS computer system by scheduling subjects research visits, documenting progress notes, initiating orders, consults, etc.	☐	☐
10. Accesses patient medical information while maintaining patient confidentiality.	☐	☐
11. Is authorized to obtain informed consent from research subject and is knowledgeable to perform the informed consent "process".	☐	☐
12. Collects and handles various types of human specimens (serum, sputum, urine, tissue, etc.)	☐	☐
13. Process and ship specimens, chemicals, reagents, etc. (*Requires Shipping of Hazardous Materials training, U.S. Department of Transportation, available through the Safety Office – Joe Jurasek)*	☐	☐
14. Enters data into databases.	☐	☐
15. Initiates intravenous (IV) therapy and administers IV solutions and medications.	☐	☐
Principal Investigator Duties	**YES**	**NO**
Serves as the Principal Investigator/Co-Principal Investigator on human subjects Research; thereby, providing oversight of the study and all study staff.	☐	☐

MISCELLANEOUS DUTIES (if applicable:

The above individual is authorized to perform in the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____

2. _____

3. _____

If Section II Bench and/or Animal research is not applicable, skip to the Signature page (Section III).

SECTION II BENCH and/or ANIMAL SUBJECT RESEARCH

Bench Routine Duties	YES	NO
1. Use and store chemicals (e.g., toxic, carcinogenic, flammable, teratogenic)	☐	☐
2. Operate routine laboratory equipment including centrifuges, safety cabinets, exhaust hoods, etc.	☐	☐
3. Use containment equipment (e.g., protective clothing, safety cabinets, etc.)	☐	☐
4. Use biomaterials, microbial or viral agents, pathogens and/or toxins.	☐	☐
5. Use molecular biology techniques (e.g., cloning, etc.) and vectors.	☐	☐
6. Use radioactive materials and/or radiation generating equipment. (*Radiation Safety approval required to order/use radioactive materials*.)	☐	☐
7. Collects, records, or analyzes animal/laboratory research data.	☐	☐
8. Process and ship specimens, chemicals, reagents, etc. (*Requires Shipping of Hazardous Materials training, U.S. Department of Transportation, available through the Safety Office – Joe Jurasek)*	☐	☐
Principal Investigator Duties	**YES**	**NO**
Serves as the Principal Investigator/Co-Principal Investigator on bench science research; thereby, providing oversight of the study and all study staff.	☐	☐

Animal Subject Routine Duties	YES	NO
1. Is knowledgeable about the ethical and safe handling of animals and performs procedures involving animals (e.g. tailing, surgery, and/or behavioral interventions). *Requires completion of the CITI Species Specific training.*	☐	☐
a. Performs special husbandry and/or practices as required.	☐	☐
b. Performs surgical procedures on small animals.	☐	☐
c. Performs surgical procedures on large animals.	☐	☐
d. Administers euthanasia for animals in approved ACORPs.	☐	☐
e. Obtains blood specimens from animals.	☐	☐
f. Administers parenteral injections (IP-intraperitoneal, SQ-subcutaneous, IM-intramuscular, IV-intravenous) I	☐	☐
g. Administers substances PO (orally).	☐	☐
h. Works with breeding colony protocols	☐	☐
2. Uses safe procedures involving animals and uses protective equipment appropriately (e.g. gloves, mask, eye protection, protective clothing).	☐	☐
3. Orders laboratory animals.	☐	☐
Principal Investigator Duties	**YES**	**NO**
Serves as the Principal Investigator/Co-Principal Investigator on animal subject research; thereby, providing oversight of the study and all study staff.	☐	☐

MISCELLANEOUS DUTIES (if applicable:

The above individual is authorized to perform in the following miscellaneous duties not otherwise specified in this Scope of Practice.

1. _____

2. _____

3. _____

Complete the Signature Page in Section III.
SECTION III SIGNATURE PAGE (*Submit along with the Section(s) applicable to the individual's Scope of Practice*)

Principal Investigator/Supervisor's Statement:

The Scope of Practice was reviewed and discussed with the personnel on the date shown below. After reviewing his/her education, competency, qualifications, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties/procedures.

Both the personnel and I are familiar with all duties/procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, all applicable facility policies and regulations.

This Scope of Practice will be reviewed annually and amended as necessary to reflect changes in the individual's duties/ responsibilities. A new Scope of Practice will be completed if the employee is assigned a new supervisor.

_____ _____
Research Personnel Date

_____ _____
Supervisor Date

The original signed Scope of Practice will be maintained in the Research Business Office. The Supervisor and Research Personnel should maintain a copy of the Scope of Practice in preparation of any change in duties and required annual review. The PI must keep a copy of all SOPs in each study's Regulatory Binder.

OFFICE USE ONLY:

_____ _____
ACOS/Research & Development Service Date

Assignment of Functional Categories (VA Form 10-0539) Instructions

This form is required to ensure each employee has the correct VA software and programs assigned to them when they in-process.

If you require access to entire patient medical records, including research records, click the second box 'Department of Veterans Affairs (VA) Researchers'.

If you will not access any patient health information that is protected by the 1974 Privacy Act and/or HIPAA, select the last block on page 1, 'Operations Support'.

Department of Veterans Affairs

Assignment of Functional Categories

Employee's Name:

Job Title: Research Assistant

Department/Service Assigned: Research

If employee falls into more than one functional category listed below, access should be granted based on the less restrictive category to meet the need of an intended purpose.

This table shows access or non access to PHI in regards to functional category, it does not show if a user needs access to their own System of Records (e.g. 24VA10P2) in order to complete their job functions. For a list of classes of people, please reference VHA Handbook 1605.02, Appendix B.

Immediate Supervisor: Check off functional category, review with employee, obtain signatures, and maintain copy in the *Supervisor's Personnel Files* (RCS 10-1, 05-3) for the individual employee. Review of Functional Category must be done on an annual basis, even if there is not a change.

	Functional Categories (Class of Persons)	**Type of Protected Health Information Accessible**	**Allowable Systems of Records for Limited Access**	**Conditions for Access to Information**
☐	Direct Care Providers	Entire Health Record		Treatment of Individuals
☐	Department of Veterans Affairs (VA) Researchers	Entire Health Record including research records		Activities as approved by an Institutional Review Board or Privacy Board
☐	Indirect Care Providers	Entire Health Record		In support of treatment of individuals
☐	Chief Business Office (CBO) Administrative	Entire Health Record		In support of CBO functions such as payment, reimbursement, income verification and eligibility benefits
☐	Health Information Support Services	Entire Health Record		Assign diagnostic codes, transcribe, file, release information, scan, and provide or input registry data
☐	Quality, Oversight and Investigations	Entire Health Record		Address medical inspections, investigations, complaint review and resolution, quality reviews, patient safety reviews, compliance, and provide congressional response
☐	Chief of Police	Limited Health Record	79VA10P2, 24VA10P2	Reviewing Patient Inquiry
☐	Police and Security Service	No Need for access to PHI		Security functions
☐	Information Security, Privacy, Compliance, VISN Staff, Patient Advocate	Entire Health Record including research records		Monitoring and tracking of security privacy and compliance issues
☐	Operations Support	No need for access to PHI		Internal operations.

	Functional Categories (Class of Persons)	Type of Protected Health Information Accessible	Allowable Systems of Records for Limited Access	Conditions for Access to Information
☐	Leadership and Management	Limited access, where necessary to complete assignment	24VA10P2, 79VA10P2, 121VA10P2 and any other system of records with national data.	Operation and managment , executive decisions for health care operations.
☐	Non Health Information Administrative Support	Limited Health Record, where necessary to complete assignment	79VA10P2, 24VA10P2	Administrative, public, and employee support
☐	Environmental Support Staff	No need for access to PHI		Maintenance of grounds and buildings
☐	Information Technology	Limited Health Record, where necessary to complete assignment	79VA10P2, 24VA10P2, 121VA10P2 and any other system of records for an IT system.	Maintenance and support of computer systems.
☐	Veterans Canteen Service	No need for access to PHI		Retail and food services for employees and Veterans
☐	Volunteer Services	Limited Health Record	79VA10P2, 24VA10P2	Transportation and other services

By signing this document I acknowledge and understand that I have been assigned the functional categories listed above and given computer access and VistA menu options if applicable to access and use Protected Health Information only in the performance of my official job duties and assigned task.

Employee's Signature:	Date:
Supervisor's Signature:	Date:

☐ Interim Review for Position Change ☐ Interim Review for Job Assignment Change

The following changes have been made to employees' functional category:

☐ No changes made, functional category and menu options to remain the same for this fiscal year.

Employee's Signature:	Date:
Supervisor's Signature:	Date:

VA Ann Arbor Healthcare System Research Service (151)
2215 Fuller Road
Ann Arbor, Michigan 48105 Fax (734) 761-7693

RELEASE OF INFORMATION AUTHORIZATION & EDUCATION AND TRAINING VERIFICATION FORM

In order for the VA Ann Arbor Healthcare System (VAAAHS) Research Service to access and verify my educational background, professional qualifications and suitability for appointment, I hereby authorize the VAAHS to make inquiries and consult with all persons, places of employment, education, malpractice carriers, State licensing boards, or other similar government and non-governmental entities who may have information bearing on my moral, ethical and professional qualifications and competence to carry out the duties outlined in my VA Research Scope of Practice. I authorize release of such information and copies of related records and/or documents to VA officials.

I authorize the VA to disclose to such persons, employers, institutions, boards or agencies identifying and other information about me sufficient to enable the VA to make such inquiries.

I release from liability all those who provide information to the Department of Veterans Affairs in good faith and without malice in response to such inquiries.

As part of the VA Research & Development credentialing process, it is necessary to verfiy my educational and professional credentials. I agree to provide the following information:

EMPLOYEE NAME (Last, First, Middle Initial)		**SOCIAL SECURITY NUMBER**
OTHER NAMES USED (MAIDEN, ETC.)		
UNIVERSITY/COLLEGE/PROGRAM ATTENDED (Use separate form for each University/Program)		
CITY/STATE/COUNTRY		
# YEARS ATTENDED	**DATES ATTENDED (to & from dates)**	**DEGREE(S) RECEIVED**
	To	
PROFESSIONAL TRAINING/EXPERIENCE		**DATES TRAINING RECEIVED**
PROFESSIONAL CERTIFICATION (bring original to research office)		**ISSUE DATE - EXPIRATION DATE**
STATE PROFESSIONAL LICENSE/REGISTRATION		**ISSUE DATE - EXPIRATION DATE**
EMPLOYEE WORK ADDRESS		**EMPLOYEE DATE OF BIRTH**
EMPLOYEE SIGNATURE		**DATE**

The VA Research Office will make every possible effort to protect the confidentiality and security of this document.

Standard Training
All Applicants

The VAAAHS requires three mandatory training modules (listed below) for every employee to complete annually. Before beginning work as a WOC employee, you must complete all three of these modules. You will be required to complete them annually in order to stay in compliance for any research project in which you participate.

1. *VA Privacy and Information Security Awareness Training and Rules of Behavior*
2. *VHA Privacy and HIPAA*
3. *Infection Control: Bloodborne Pathogens and Tuberculosis*

All three modules are accessed via the VA Talent Management System (TMS). This system offers web-based training to VA employees and its partners.

FOR PERSONS ALREADY REGISTERED IN TMS

If you are already registered in TMS and have taken courses in the past, you do not need to register, again. Please contact Christina Wayne (christina.wayne@va.gov or 734-845-5600) to ensure you have the correct courses assigned to you.

FOR PERSONS NOT REGISTERED IN TMS

You must self-enroll for a profile on the VA TMS site by visiting https://www.tms.va.gov/plateau/user/login.jsp. Once there, follow the steps below to create a profile, launch mandatory training and complete content prior to your processing appointment.

****The **Infection Control** training must be completed on a **VA computer** due to firewall issues. If you do not have access to a VA computer, you can complete the training at the Research Office the day of your appointment.*

1. Step-by-Step Instructions

1. From a computer, launch a web browser and navigate to https://www.tms.va.gov/plateau/user/login.jsp
2. Click the [**Create New User**] link in the menu below the TMS logo and login fields.
3. Select the button for '**WOC**'.
4. Click the [**Next**] button.
5. Enter the appropriate information in the fields below.
   a. My Account Information:
      i. Create **Password** Follow the guidelines presented on screen.
      ii. Re-enter **Password**
      iii. **Security Question**
      iv. **Security Answer**
      v. Re-enter **Security Answer**
      vi. **Social Security Number** Your SSN is used only as a unique identifier in the system to ensure users do not create multiple profiles. The SSN is stored in a Private Data Table that cannot be accessed anywhere via the VA TMS interface. It is securely transferred to a VA database table inside the VA firewall where it can be confirmed, if necessary, by appropriately vested system administrators and/or Help Desk staff.
      vii. Re-enter **Social Security Number**
      viii. **Date of Birth**
      ix. **Legal First Name**
      x. **Legal Last Name**
      xi. **email Address** Enter your work or school address. If you have a VA email address, use this one. Your email address will be your user ID.
      xii. Re-enter **email Address**
      xiii. **Phone Number** – Enter a number where you can be reached by VA staff if issues arise with the self-enrollment process or in other circumstances.
   b. My Job Information. Enter the information below **EXACTLY** as presented.
      i. **VA City** – Enter **Ann Arbor**
      ii. **VA State** – Select Michigan (MI)
      iii. **VA Location Code** – Select **ANN**
      iv. **VA Point of Contact First Name** – Enter **Christina**
      v. **VA Point of Contact Last Name** – Enter **Wayne**
      vi. **VA Point of Contact eMail Address** – Enter **christina.wayne@va.gov**
      vii. **VA Point of Contact Phone Number** – Enter **734-845-5600**
      viii. Check the **HIPPA Training Required** check box.

6. Click **'Submit'** when complete. Your profile will immediately be created. Check your UserID when it displays on the confirmation page. Click on the **'Continue'** button to load your **'To-Do List'**. This will populate with mandatory training.

2. Launching and Completing the Content

1. Mouse over the title of the available item in the **To-Do List.**
2. Click the [**Go to Content**] button in the pop-up window that appears.
3. Complete the content following the on-screen instructions.
4. Exit the course.
5. Click on the '**Completed Work**' pod on the lower right side of your TMS screen.
6. Move your mouse to hover over the title of your courses to print the certificates. Click on '**Print Completion Certificate**' for all the mandatory training required for the WOC application.
7. Remember, your Infection Control training will not appear in your To-Do List. The Research Office will assign this training when you call to schedule your processing appointment. This training must be done on a VA computer.

3. Trouble-shooting and Assistance

The **Check System** link on the VA TMS is an automated tool that confirms the existence of basic, required software on the computer you are using to complete this training. If one of the components is not in compliance with the requirements, a red '**X**' will appear next to the Check System link. If this happens with your computer, please follow the instructions to bring your computer up to the standards that will work with the VA TMS or move to another computer.

*****If you do not have a Social Security Number, or if you experience any difficulty creating a profile or completing the mandatory content, contact the VA MSE Help Desk at 1-888-501-4917 or via email at VAMSEHelp@gpworldwide.com.**

Laboratory Training & Forms

NEW VA RESEARCH LABORATORY WORKERS

All VA Research Laboratory workers must complete the following training in CITI and complete the Laboratory Employee Safety Checklist on the following page.

Introduction to VA Biosecurity Concepts is accessed via the Collaborative Institutional Training Initiative (CITI) at the University of Miami. This is a one time requirement.

1. Navigate to **https://www.citiprogram.org**
2. Click 'Register' in the 'Create an account' box.
3. Select your Organization Affliation by typing **VA Ann Arbor, MI-506** and selecting it from the drop down.
4. Click 'Continue to Step 2'.
5. Fill in the Personal Information as requested and then click 'Continue to Step 3'.
6. Create your Username, Password and Security Question following the instructions on the screen. Click 'Continue to Step 4'.
7. Fill in the required information for Country of Residence, Gender, Ethnicity and Race. Click 'Continue to Step 5'.
8. Answer the questions for Continuing Education Units. Click 'Continue to Step 6'.
9. Fill in the required information for Instiutional email address (VA or university email), Gender, Department (Research), Role in Research (choose from the drop down menu). Click 'Continue to Step 7'.
10. Human Subjects Research = Click appropriate option for your study (option one or two).
11. Serving on VA IACUC or university IACUC = Click appropriate option for you.
12. Utilize laboratory animals = Click appropriate option for your study.
13. Answer Questions 5 and 6, as required.
14. Biosecurity training = 'I am a new VA or VA foundation employee and have NOT taken required VA training'.
16. Post-Approval Monitoring course = click appropriate button.
17. Click 'Complete Registration'.
18. Click 'Finalize Registration'.
19. Complete required course work and print completion certificates for in-processing appointment.

If you have questions or experience difficulties registering, contact the following people:

1. WOC Coordinator/Program Support Assistant, Christina Wayne, 734-845-5600
2. R&D Coordinator, Len Cooke, 734-845-5602
3. Human Studies Coordinators, Cathy Kaczmarek or Terry Robinson, 734-845-3440
4. Animal Studies & Research Safety Coordinator, Carolyn Slusher, 734-222-7981

Research Office Fax = 734-845-3241
VA Mail Code = 151
UM Mail Code = Zip 2399
US Mail Address = 2215 Fuller Road, 48105

VAAAHS Research Service (151)

LABORATORY EMPLOYEE SAFETY TRAINING CHECKLIST

Employee Name	Supervisor	**WOC** ☐ **VA Employee** ☐	Start Date

All Laboratory personnel must complete annual safety training. Complete the items relevant to your lab area with your supervisor.

☐	**1. Location and *use* of Life Safety Equipment:**	☐	5. **MSDS Sheets** (Material Safety Data Sheets) - location and use
☐	**a. Fire Safety** 1. Fire Emergency Plan - RACE 2. Pull Stations - location & fire codes 3. Fire Extinguishers - location & use	☐	6. **Review the Hazardous Materials Management Plan (S-2)**
☐	**b. Minimum Accessibility Requirements** 1. Maintain a 48" corridor width 2. Storage at least 18" from sprinkler heads 3. Maintain 36" semi-circle of access to electrical panels	☐	7. **Safety Management Program (S-3)**
☐	**c. Showers, Eye Washes** (location, use, functionality check & monthly update of inspection tags for eye washes)	☐	8. **Exposure Control Plan For Bloodborne Pathogens (S-4)** a. To work with human blood/body fluids b. Post Exposure Evaluation and Follow-up.
☐	**d. Spill Kits** for Acid, Caustic, Flammable, Blood & Body fluids (how to use, fully stocked kits) 1. Replacement supplies	☐	9. **Emergency Preparedness Plan & DoD Contingency Plan (S-5)**
☐	**e. Safety equipment specific to your lab,** including personal protection equipment (PPE) 1. Lab coats 2. Eye, Face, Hand, Foot, Head	☐	10. **Operation of equipment** (such as sterilizers and centrifuges) a. Location of operation Manual b. Documented User Training
☐	**2. Medical Center Safety Policies Manual** (review location & check documentation for each person who works in the lab has reviewed manual) (Also located on "T" Drive; Public/Policies/Policies-Current/Safety	☐	11. **Safety of Personnel Engaged In Research** VHA Handbook 1200.08
☐	3. **VA Research Safety Policies On-Line** http://www.annarbor.research.va.gov/ANNARBORRESEARCH/policies.asp	☐	12. **Specific job related hazards** a. Gas cylinder storage and handling b. Moving chemicals to storage c. Glass d. Chemical inventory e. Biohazard
☐	4. **Radiation Safety and ALARA Program (S-1)**	☐	**NO FOOD OR DRINKS IN LABS** No beverage containers of any kind on benches No food in laboratory refrigerators **VIOLATORS WILL BE FINED $500**

Employee Signature	Date	Supervisor Signature	Date

Human Subjects Research Training & Forms

NEW VA HUMAN SUBJECTS RESEARCH WORKERS

All VA Human Subjects Research workers must complete the following training in the Collaborative Institutional Training Initiative (CITI) at the University of Miami.

VA Human Subjects Training (HST) and ***Good Clinical Practices (GCP)*** is a required VA research course that must be completed every three years. If you fail to retake the course by your renewal date, you **MUST** stop all work on all research studies/projects.

To complete this combined course, perform the following steps below.

1. Navigate to **https://www.citiprogram.org**
2. Click 'Register' in the 'Create an account' box.
3. Select your Organization Affliation by typing **VA Ann Arbor, MI-506** and selecting it from the drop down.
4. Click 'Continue to Step 2'.
5. Fill in the Personal Information as requested and then click 'Continue to Step 3'.
6. Create your Username, Password and Security Question following the instructions on the screen. Click 'Continue to Step 4'.
7. Fill in the required information for Country of Residence, Gender, Ethnicity and Race. Click 'Continue to Step 5'.
8. Answer the questions for Continuing Education Units. Click 'Continue to Step 6'.
9. Fill in the required information for Instiutional email address (VA or university email), Gender, Department (Research), Role in Research (choose from the drop down menu). Click 'Continue to Step 7'.
10. Human Subjects Research = Click option two (involved in human subjects, never completed training).
11. Serving on VA IACUC or university IACUC = No
12. Utilize laboratory animals = No
13. Skip Questions 5 and 6.
14. Biosecurity training = 'I am a new VA or VA foundation employee and have NOT taken required VA training' if you are working in a lab.
16. Post-Approval Monitoring course = click appropriate button.
17. Click 'Complete Registration'.
18. Click 'Finalize Registration'.
19. Complete required course work and print completion certificates for in-processing appointment.

If you have questions or experience difficulties registering, contact the following people:

1. WOC Coordinator/Program Support Assistant, Christina Wayne, 734-845-5600
2. R&D Coordinator, Len Cooke, 734-845-5602
3. Human Studies Coordinators, Cathy Kaczmarek or Terry Robinson, 734-845-3440
4. Animal Studies & Research Safety Coordinator, Carolyn Slusher, 734-222-7981

Research Office Fax = 734-845-3241
VA Mail Code = 151
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Animal Subjects Research Training & Forms

NEW VA ANIMAL SUBJECTS RESEARCH WORKERS

All VA Animal Subjects Research workers must complete the following training in the Collaborative Institutional Training Initiative (CITI) at the University of Miami. Additionally, animal research workers must complete the 'WOC Occupational Health & Safety Survey for Personnel with Laboratory Animal Contact'.

Working with the IACUC and ***Working with (species) in Research Setttings*** are required VA research courses that must be completed every three years by all animal researchers. If you fail to retake the courses by your renewal date, you **MUST** stop all work on all research studies/projects.

Post Procedure Care of Mice and Rats is required if you will be performing surgery and/or caring for rodents after survival surgery. This course must be completed every three years. If you fail to retake the courses by your renewal date, you **MUST** stop all work on all research studies/projects.

To complete these courses, perform the following steps below.

1. Navigate to **https://www.citiprogram.org**
2. Click 'Register' in the 'Create an account' box.
3. Select your Organization Affliation by typing **VA Ann Arbor, MI-506** and selecting it from the drop down.
4. Click 'Continue to Step 2'.
5. Fill in the Personal Information as requested and then click 'Continue to Step 3'.
6. Create your Username, Password and Security Question following the instructions on the screen. Click 'Continue to Step 4'.
7. Fill in the required information for Country of Residence, Gender, Ethnicity and Race. Click 'Continue to Step 5'.
8. Answer the questions for Continuing Education Units. Click 'Continue to Step 6'.
9. Fill in the required information for Instiutional email address (VA or university email), Gender, Department (Research), Role in Research (choose from the drop down menu). Click 'Continue to Step 7'.
10. Human Subjects Research = No/not involved
11. Serving on VA IACUC or university IACUC = yes if member, no if not member
12. Utilize laboratory animals = Yes
13. Check each species you will work with.
14. Perform or supervise survival surgery in rodent species = Click appropriate button.
15. Biosecurity training = 'I am a new VA or VA foundation employee and have NOT taken required VA training'.
16. Post-Approval Monitoring course = click appropriate button.
17. Click 'Complete Registration'.
18. Click 'Finalize Registration'.
19. Complete required course work and print completion certificates for in-processing appointment.

If you have questions or experience difficulties registering, contact the following people:

1. WOC Coordinator/Program Support Assistant, Christina Wayne, 734-845-5600
2. R&D Coordinator, Len Cooke, 734-845-5602
3. Human Studies Coordinators, Cathy Kaczmarek or Terry Robinson, 734-845-3440
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Research Office Fax = 734-845-3241
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Occupational Health and Safety Program (OHSP) for Personnel with Laboratory Animal Contact

Each VA facility with an animal research program must establish an OHSP to protect the personnel who are involved in animal research, or who are otherwise at risk of exposure to animals or their (unfixed) tissues or fluids. The purpose of this brochure is to explain the components of the OHSP, and provide information on how you can minimize the chance of any adverse health effects from working with laboratory animals.

Who should participate? All personnel who work with animals or unfixed tissues in VA research must be given the opportunity to enroll in the OHSP at the VA facility at no charge. Furthermore, individuals who may have intermittent animal exposure must also be given the opportunity to enroll (e.g. IACUC members, housekeeping staff, physical plant, VA police officers) You may choose to decline to receive OHSP services that aren't required to protect the health of personnel and animals. To enroll, contact your VA research administrators or Occupational Health.

What is included? The services you receive will depend on the type and frequency of exposure, and your medical history. A medical surveillance questionnaire is often used to assess your individual risk factors. A health professional will review your responses and determine the frequency and type of interaction (tuberculin testing, immunizations, etc.) with the OHSP.

ANIMAL EXPOSURE RISKS

The hazards associated with handling animals can be divided into three categories:

1) Physical Hazards. Examples of such hazards include animal bites and scratches, sharps injuries, injuries associated with moving cages or equipment, and adverse consequences from excessive noise or accidental exposure to workplace. The key to preventing these injuries is proper training and meticulous attention to proper work practices.

- Use appropriate techniques for animal handling and restraint.
- Do not recap needles and dispose of sharps in approved containers.
- Employ good ergonomic practices to avoid muscle sprains and repetitive motion injuries.
- Wear recommended personal protective equipment (PPE) such as a lab coat, gloves, eye and hearing protection.

2) Allergies. Allergic reactions to animals are among the most common conditions that affect the health of workers exposed to laboratory animals. Sneezing, itchy eyes, and skin rashes are typical clinical signs, but in serious cases, asthma or anaphylaxis may occur. Allergens include urine, dander, and saliva, especially from rodents. You can limit exposure to allergens by using appropriate PPE and using safe work practices.

Protect Yourself from Allergies!

- Work in a clean, well-ventilated environment.
- Wear appropriate PPE such as a lab coat and disposable gloves, and **never rub your face or eyes** until you have removed your gloves and washed your hands thoroughly.
- It may be helpful to wear a surgical-type mask to reduce airborne exposure in animal rooms. If you need a respirator, you must be medically cleared, fit tested and trained annually.

3) Zoonotic diseases. Zoonotic diseases are those that can be transmitted from animals (or animal tissues) to humans. Although a substantial number of animal pathogens may cause disease in humans, zoonotic diseases are not common in modern animal facilities, largely because of prevention, detection, and eradication programs.

Unfortunately some infections of animals may produce serious disease in humans *even when the animals themselves show few (if any) signs of illness*. Therefore, you must be aware of possible consequences when working with each species of animal and take precautions to minimize the risk of infection. **If you experience flu-like symptoms or other signs of illness, be sure to tell your doctor that you work with animals, just in case your illness is related to your work with animals.**

Prevention. Common sense steps that can be taken to lessen zoonotic disease risk include:

- Do not eat, drink, or apply cosmetics or contact lenses around animals.
- Wear gloves when handling animals or their tissues.
- Use proper manual and/or anesthetic restraint when working with fractious animals and/or administering hazardous agents.
- Work in pairs whenever possible.

- **Do not recap used needles!** Whenever possible, use safety devices, activate the safety feature as soon as possible and dispose them promptly in a biohazard "sharps" container.
- When performing procedures such as bedding changes, blood or urine collections, or necropsies, work in biological safety cabinets or wear specialized PPE as directed.
- **Consult your supervisor, the Safety Officer, or Occupational Health Health if you need additional training at any time.**

WHAT YOU SHOULD KNOW

About Bites, Scratches, and other Injuries…

Contact your Supervisor and Occupational Health immediately if you are bitten or scratched, if you injure yourself while performing your job, or if you experience unusual disease symptoms.

If you are Pregnant…

Working with hazardous agents and toxic chemicals is discouraged during pregnancy. Consult Employee Health and your personal physician for advice about working safely during pregnancy. Toxoplasma is an infectious agent sometimes shed in cat feces, and it can infect the fetus of pregnant women that do not have acquired immunity. Pregnant women should generally avoid any contact with cat feces or litter boxes.

If you work with Nonhuman Primates…

Diseases of nonhuman primates (NHPs) are often transmissible to humans. Although, several NHP viruses may cause disease in humans, *Herpesvirus simiae* (B-virus) is of greatest concern. This virus occurs naturally in macaques such as rhesus and cynomolgus monkeys. Infected monkeys usually show no clinical signs, but the virus may cause fatal brain infections in humans. Transmission to humans occurs via exposure to contaminated saliva, secretions, or tissues. This typically occurs as a result of a bite or scratch; transmission may also occur via splashes that come in contact with mucous membranes or via injuries caused by contaminated equipment. Proper work practices are essential to preventing exposure.

- Wear PPE, (i.e. protective outer garments, gloves, face mask, and eye protection).
- Anesthetize monkeys whenever possible before handling.
- In the event of possible exposure, obtain medical attention immediately. Instructions for treating wounds and obtaining medical attention must be posted in each nonhuman primate area.

Tuberculosis may be transmitted both from humans to animals and from animals to humans. NHPs and individuals in contact with them must be screened for tuberculosis annually. *Shigella*, *Campylobacter*, *Salmonella*, and *Entamoeba histolytica* cause diarrhea in NHP species and may cause similar problems in humans exposed to NHP feces. Infection is best prevented by protection from aerosols, the use of gloves, and careful hand washing.

Simian immunodeficiency virus (SIV) is closely related to HIV, the human AIDS virus, and can, on rare occasions, affect macaques. Some evidence suggests it may infect humans as well, so measures should be taken to prevent contact with monkey blood or blood products.

If you work with Dogs or Cats…

The main risks associated with working with dogs and cats are bites and scratches. Sometimes scratches or bites can result in infections. Cat bites can result in particularly severe infections. Cat scratch fever (Bartonellosis) is caused by a rickettsial organism and is characterized by flu-like symptoms and swollen lymph nodes.

Rabies

The likelihood of contracting rabies as a result of a bite is now very low because research dogs and cats are typically vaccinated for rabies. Nevertheless, it is recommended that persons in contact with dogs or cats be vaccinated against rabies.

If you work with Farm Animals…

Q fever, a potentially serious disease caused by *Coxiella burnetii*, is carried by ruminants and shed abundantly from the placental membranes of sheep. Human exposure can result in pneumonia and other symptoms. Sheep used in research should be assumed to be infected, and careful measures taken to prevent transmission to humans. All individuals working with pregnant laboratory sheep should wear gloves, respiratory protection, and protective outerwear.

If you work with Rodents or Rabbits…

Allergies are common among personnel who work with rodents (e.g., mice, rats, guinea pigs, hamsters) and rabbits. If you have pre-existing allergies or if you experience a runny nose, itchy eyes, or skin rashes when working around these species you should report these symptoms immediately to Occupational Health. Measures can be taken to limit your exposure to allergens, thereby reducing the severity of symptoms and decreasing the likelihood that symptoms will worsen.

Rodents and rabbits obtained from commercial sources have a low risk of transmitting zoonotic diseases. However, animals caught in the wild can harbor a variety of bacterial, viral, fungal, and parasitic infections that can constitute a significant hazard to personnel.

If you work with Hazardous Agents…

The proper use of hazardous biological, chemical, and physical agents in animals depends on careful planning, proper training, and careful attention to prescribed work practices. Signs should be posted indicating the nature of the hazard, necessary precautions, and

emergency contact information. The PPE needed depends on the agent in use, but in all cases gloves should be worn and hands should be washed after handling potentially contaminated materials. A biological safety cabinet should be used when handling infectious materials, especially if there is a potential for generation of aerosols, and a fume hood should be used when handling toxic chemicals or radioactive materials. The measures must be appropriate for the specific hazard, as determined by the Safety/Biosafety Officer in consultation with the investigator, the Subcommittee on Research Safety, and the veterinarian.

FOR FURTHER INFORMATION

The services offered in your program may differ somewhat from those described in this pamphlet. For further information, contact your research administrators or Occupational Health. More guidance in this area can be found in VHA Handbook 1200.07, "Use of Animals in Research."

Occupational Health and Safety Program (OHSP)

As a researcher assigned to an animal study, you must be enrolled in either the VA OHSP or the University of Michigan OHSP.

In order to be enrolled in the UofM OHSP, you must have completed their medical questionnaire, be enrolled in eRAM and completed the training in ULAM. If you have not done all of these, you will be enrolled in the VA OHSP.

If you are enrolled in the UofM OHSP, please complete the first two pages of OHSP paperwork and bring them to your WOC processing appointment.

If you are attached to an animal study, but do not interact with animals or any animal material, complete the first two pages and return them to the Research Program Support Assistant.

If you are going to enroll in the VA OHSP, complete all five pages and bring them to your WOC processing appointment.

Occupational Health and Safety Program (OHSP) Explanation and Acknowledgement of Program

1. What does the VA require for an OHSP in an animal research program?

The VA requires each VA facility with an animal research program to develop a written policy establishing an OHSP to protect the personnel who are involved in animal research or who are otherwise at risk of exposure to animals or their (unfixed tissues or fluids. This includes protection from risks related to the use of hazardous agents specifically used in research animals. The program should be tailored to individuals according to the risks they will encounter and their medical history (VHA Handbook 1200.07, *Use of Animals in Research*, paragraph 10 and Appendix C, 23 November 2011, and *Occupational Health and Safety in the Care and Use of Research Animals*, The National Academies Press, 1997).

2. Who must be allowed to participate in the VA OHSP?

All Federal paid employees, without compensation (WOC) employees and other non-Federal personnel who work with animals or unfixed tissues used in VA research **MUST** be given the opportunity to participate equally in the OHSP at the VA facility at no charge, unless the IACUC determines that such personnel are enrolled in an alternate program (e.g., an affiliate's program) that complies with Public Health Service (PHS) policy. In addition, the following individuals who have intermittent contact with animals or the animal facility must also have the opportunity to enroll at no charge:

a. IACUC voting members (including the non-affiliated and non-scientist member) and non-voting participants who enter the animal facility as part of the IACUC semi-annual evaluation of the animal care and use program and facilities.

b. Maintenance, engineering, and housekeeping perosnnel who enter the VMU intermittently.

c. Other personnel, such as the VA Police or security personnel, who could have need to enter the VMU in an emergency. Such personnel should be identified in consultation with occupational health medical professionals.

d. Employees whose duties require significant contact with dogs, cats, bats, or wild carnivores must be provided the opportunity of receiving pre-exposure rabies immunization in accordance with current CDC recommendations. The medical facility must procure and administer the vaccine at no cost to employees requesting immunization.

3. Who may decline participation?

Personnel working in VA animal research facilities MUST participate in the VAMC medical surveillance program or an approved affiliated program (e.g., University of Michigan), but may decline optional services. Personnel may decline to receive services not required by the VA facility to protect the health of the animals or other personnel (e.g., TB testing or chest radiography). Personnel who decline optional services are considered to be enrolled in the OHSP as long as the VA facility documents that they were given the opportunity to receive these services.

I have read and understand the 'Occupational Health and Safety Program (OHSP) for Personnel with Laboratory Animal Contact' brochure and the VA's OHSP information. I understand that I am automatically enrolled in the OHSP. In the unlikely event that I should require any medical services, I reserve the right to decline or 'Opt out' of on-site medical care and see my own medical provider. I understand that I will be required to annually complete an OHSP Medical Questionnaire distributed by VAAAHS Employee Health personnel.

I participate in the University of Michigan Occupational Health and Safety Program for Personnel Working with Animals. No

Name _____ Date _____

Signature _____ Principal Investigator _____

Experience Working with Animals

Name Email

PI Lab Phone

Lab Location

Animal Contact

1. What species of animals will you be exposed to/work with? (This includes direct contact with animals, animal tissues and/ or wastes, and animal enclosures)

   ☐ Mice ☐ Rats ☐ Rabbits ☐ Guinea Pigs ☐ Dogs ☐ Cats ☐ Frogs ☐ Other (specify)

2. What kind of contact will you have? (Check all that apply)

   ☐ Direct contact with animals ☐ Fixed tissue ☐ No contact at all

   ☐ Direct contact with non-fixed or non-sterilized animal tissues, fluids or wastes

   ☐ Direct contact with non-sanitized animal caging or enclosures

   ☐ Service support to animal equipment, devices, and/or facilities

3. I will be involved with: ☐ Surgical Preparation ☐ Surgical Procedures ☐ Post Surgery Care

   ☐ Routine Care (special feeding, observations) ☐ Other (specify)

4. I have experience working with animals as a result of

   ☐ Attending animal workshops (dates attended)

   ☐ Undergraduate/Graduate School ☐ Conducted previous research (# of years)

5. Do you or will you handle animals that have been given infectious biohazards? No

   If yes, please provide the following information Infectious agent

   CDC Class of agent

   Date of infectious biosafety training

6. **Do you or will you handle animals that have been given chemical hazards?** No

   If YES, please describe the hazard.

7. Do you or will you handle animals that have been exposed to or given radiation hazards? No

   If yes, please describe the type of radiation hazard. Other **Radiation Training Date**

8. Do you/will you work with species of or biological material from non-human primates? No

9. Do you/will you work with recombinant DNA technology? No

   If yes, does the research involve techniques in which viable recombinant DNA-containing micro-organisms are used to infect animals that then require Biosafety Level 3 containment? No

Signature _____ Date _____

PI Signature _____ Date _____

Confidential Medical Information (when filled in)

Significant Biological Agent or Animal Contact Health Surveillance Questionnaire

Name _____ SSN _____

Service _____ Date of Birth _____

Gender Male Phone _____

Email _____ Preferred Language _____

Projected Duration of Duties _____

Previous Evaluation at Employee Health? No

Status (Check all that apply)

- ☐ VA Staff
- ☐ UM Faculty
- ☐ WOC
- ☐ Animal Handler
- ☐ Veterinarian
- ☐ Research Technician
- ☐ Research Assistant
- ☐ Other (specify) _____

Do you have contact with animals outside of work? No

If 'Yes', please list all species _____

Allergy History

List any allergies to medications _____

List reactions to medications _____

Do you have any of the following? (Check all that apply)

- ☐ Chronic cough
- ☐ Hay fever
- ☐ Skin rash
- ☐ Asthma
- ☐ Allergic rhinitis (runny nose)
- ☐ Allergic conjunctivitis (itchy, water eyes)
- ☐ Chronic allergies (food, pollen, dust)
- ☐ Natural parent and/or sibling with allergies to animals or their substances

Are you allergic to any of the following? (Check all that apply)

- ☐ Dogs
- ☐ Cats
- ☐ Swine
- ☐ Alfalfa
- ☐ Rats or Mice
- ☐ Rabbits
- ☐ Guinea Pigs
- ☐ Trees
- ☐ Birds (feathers)
- ☐ Farm Animals
- ☐ Sheep (wool)
- ☐ Weeds
- ☐ Primates
- ☐ Latex
- ☐ Chemicals
- ☐ Other _____
- ☐ Grasses
- ☐ Wood

Do you have any of the following symptoms that you feel are caused by, or made worse, because of your work with laboratory animals?

- ☐ Cough
- ☐ Wheezing
- ☐ Chest tightness
- ☐ Hives
- ☐ Sneezing
- ☐ Shorness of breath
- ☐ Rash
- ☐ Runny nose
- ☐ Watery, burning, or itchy eyes

Other Health Information

Have you been told by a physician that you have an immune compromising medical condition or are taking medications that impair your immune system (steroids, immunosuppressive drugs, chemotherapy)? No

If yes, list medications/conditions. _____

Are you currently pregnant or plan to become pregnant within the next year? Prefer not to

List any other conditions, medications, or concerns the provider should know about.

I verify that all information is accurate and that I have referred to and read all pertinent information related to the animals that I come in contact with.

Signature

Date

Name _____

Immunization Record

Enter the date of most recent vaccination/booster/blood test. Enter 'ND' for never done if the vaccination or test was never performed. Enter '?' if you have had the vaccination/test but cannot recall the date.

Measles _____ Hepatitis A _____

Mumps _____ Hepatitis B _____

Rubella _____ Smallpox (Vaccinia) _____

Tetanus _____ Yellow Fever _____

Rabies _____ Toxoplasmosis _____

Q Fever _____ BCG _____

CMV _____ Varicella (chickenpox) _____

Tuberculosis / PPD Skin Testing _____ N/A

If positive, date of last chest x-ray _____

If positive in the past, are you having any of the following symtoms? (Check all that apply)

☐ Fever ☐ Chronic Cough ☐ Bloody Sputum ☐ Shortness of Breath ☐ Weight Loss