

VA Ann Arbor Healthcare System  
Research Service (151)

# **NEW Without Compensation Applicant (WOC)**



Updated - November, 2021

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

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

The VAAHS 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 participate in the unique research 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.

## Required Forms Checklist

### **Human Subjects Research:**

- ☐ New Employee Information Form
- ☐ Scope of Practice
- ☐ Assignment of Functional Categories (VA Form 10-0539)
- ☐ Research Credentialing
- ☐ Intellectual Property Agreement
- ☐ Immunization Record **(Sent in separate Employee Health Package)**

### **Animal Subjects Research**

- ☐ New Employee Information Form
- ☐ Scope of Practice
- ☐ Assignment of Functional Categories (VA Form 10-0539)
- ☐ Intellectual Property Agreement
- ☐ OHSP Explanation and Acknowledgement of Program
- ☐ Animal Contact Questionnaire **(Sent in separate Employee Health Package)**
- ☐ Significant Biological Agent or Animal Contact Health Surveillance Questionnaire **(Sent in separate Employee Health Package)**
- ☐ Immunization Record **(Sent in separate Employee Health Package)**
- ☐ Laboratory Employee Safety Training Checklist – **TO BE COMPLETED AFTER YOUR FIRST DAY OF WORK AND RETURNED TO ZHOIE BIGHAM**

### **Laboratory Research:**

- ☐ New Employee Information Form
- ☐ Scope of Practice
- ☐ Assignment of Functional Categories (VA Form 10-0539)
- ☐ Intellectual Property Agreement
- ☐ Immunization Record **(Sent in separate Employee Health Package)**
- ☐ Laboratory Employee Safety Training Checklist – **TO BE COMPLETED AFTER YOUR FIRST DAY OF WORK AND RETURNED TO ZHOIE BIGHAM**

**\*Information on required trainings for research will be provided throughout this packet. Please be sure to carefully read instructions and keep ALL training information handy for future reference.**

# WOC Application Instructions

July 2021

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 information/requirements for all applicants
3. **Human Research** – Training/information required for all applicants working on human research studies/protocols/projects, to include data analysis, human subject contact, human tissue contact, human fluids contact.
4. **Laboratory Workers** – Training/information required for all applicants working in laboratories of any kind.
5. **Animal Research** – Training/information required for all applicants working on animal studies/protocols/projects, no matter your role.

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 Human Resources (unless the form specifically indicates otherwise).

**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 have been completed by HR.

Once you have completed all of the required forms, please send them to Zhoie Bigham at [Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@va.gov). Once Zhoie has received your packet, she will provide you with instructions for setting up your appointment to get your PIV card.

For your PIV Appointment, please bring:

1. Two forms of identification (please see the PIV credential Identity verification matrix)

# PIV Credential Identity Verification Matrix

All identity source documents shall be bound to the applicant and shall be neither expired or cancelled. **PIV and Non-PIV credentials require two forms of identification, one primary and one secondary. The secondary identity source document may be from the primary or secondary list, but if from the primary list it cannot be of the same type as the primary identity source document example.**

Flash Badges may be issued following review of a single primary or secondary identity document including applicant photograph. [FIPS 201-2](#)

Primary Identity Source Document	Secondary Identity Source Document
<ul style="list-style-type: none"><li>• A U.S. Passport or U.S. Passport Card</li><li>• A Permanent Resident Card or Alien Registration Receipt Card (Form I-551)</li><li>• A foreign passport</li><li>• An Employment Authorization Document that contains a photograph (Form I-766)</li><li>• A Driver's license or ID card issued by a State or possession of the United States provided it contains a photograph</li><li>• A U.S. Military card</li><li>• A U.S. Military dependent's ID card</li><li>• A PIV Card</li></ul>	<ul style="list-style-type: none"><li>• A U.S. Social Security Card issued by the Social Security Administration</li><li>• An original or certified copy of a birth certificate issued by a state, county, municipality authority, possession or outlying possession of the U.S. bearing an official seal</li><li>• An ID card issued by a federal, state, or local government agency or entity, provided it contains a photograph</li><li>• A voter's registration card</li><li>• A U.S. Coast Guard Merchant Mariner Card</li><li>• A Certificate of U.S. Citizenship (Form N-560 or N-561)</li><li>• A Certificate of Naturalization (Form N-550 or N-570)</li><li>• A U.S. Citizen ID Card (Form I-197)</li><li>• An Identification Card for Use of Resident Citizen in the United States (Form I-179)</li><li>• A Certification of Birth Abroad or Certification of Report of Birth issued by the Department of State (Form FS-545 or Form DS-1350)</li><li>• A Temporary Resident Card (Form I-688)</li><li>• An Employment Authorization Card (Form I-688A)</li><li>• A Reentry Permit (Form I-327)</li><li>• A Refugee Travel Document (Form I-571)</li><li>• An Employment authorization document issued by Department of Homeland Security (DHS)</li><li>• An Employment Authorization Document issued by DHS with photograph (Form I-688B)</li><li>• A driver's license issued by a Canadian government entity</li><li>• A Native American tribal document</li></ul>

# IMPORTANT ONBOARDING PROCESS



**After submitting all your of forms to Research you will receive an email from our HR department, the email will come from USAJobs.gov, offering you a tentative offer for employment. You will need to go to USA Jobs, create an account, and follow all the prompts to accept this offer.**

**Afterwards you will need to go get fingerprinted, conduct a health clearance with employee health, and complete a background check. The background check will be emailed to you from eQIP, it is an electronic questionnaire for your investigation. If you do not receive either email with-in 7 days of processing through Research please reach out to Zhoie Bigham, WOC coordinator, at [Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@va.gov).**

**Once all those are completed, a firm offer will be sent with a date and time that HR is available for you to sign the SF-61 Affidavit. As soon as SF-61 is signed, employee may immediately begin their employment here as a WOC. If your doing animals studies, you will need to also conduct a physical with our employee health before you can start.**

# **Administrative Forms**



# 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 to which projects they are assigned.

1. New Employee Information form
2. Scope of Practice
3. Functional Categories
4. Research Credentialing

## RESEARCH SERVICE NEW EMPLOYEE INFORMATION SHEET

EMPLOYEE NAME \_\_\_\_\_

OTHER NAMES USED (maiden name, aliases, AKA): \_\_\_\_\_

DATE OF BIRTH: \_\_\_\_\_

PLACE OF BIRTH (city, state, province, country): \_\_\_\_\_

SOCIAL SECURITY NUMBER: \_\_\_\_\_

CURRENT RESIDENTIAL ADDRESS: \_\_\_\_\_

HOME OR CELLPHONE NUMBER: \_\_\_\_\_ ☐ Home ☐ Cell

U.S. CITIZEN: ☐ NO ☐ YES

GENDER (as indicated on government issued ID): ☐ Male ☐ Female

Degree: \_\_\_\_\_ University/Program Attended: \_\_\_\_\_ Completion Date: \_\_\_\_\_

START DATE: \_\_\_\_\_ Job Title: \_\_\_\_\_

EMPLOYEE SUPERVISOR: \_\_\_\_\_

BUILDING AND ROOM NUMBER WHERE EMPLOYEE CAN BE FOUND MOST FREQUENTLY: \_\_\_\_\_

WORK ADDRESS (If off-site) \_\_\_\_\_

DOES EMPLOYEE REQUIRE PROXY CARD ACCESS TO RESTRICTED AREAS (e.g. Bldg 22 or 31)? ☐ NO ☐ YES

WHICH AREAS? \_\_\_\_\_

WORK NUMBER WHERE EMPLOYEE CAN BE REACHED MOST FREQUENTLY: \_\_\_\_\_

Does the employee need to have a VA computer network account? ☐ NO ☐ YES

If yes, what applications/networks will the employee need access to (check all that apply)?

☐ Electronic Health Record ☐ Remote Access/VPN ☐ None ☐ Other \_\_\_\_\_

Provide an e-mail address to which we can send information \_\_\_\_\_

**Will the employee:** (please check ALL that apply)

- |                                                                                                      |                                                                         |
|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| 1. Work on-site at VA or VA-leased space                                                             | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 2. Work with chemicals?                                                                              | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 3. Work with/in a lab that houses radioactive materials?                                             | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 4. Work with any biohazardous agents?                                                                | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 5. Work with formaldehyde or formaldehyde-based chemicals?                                           | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 6. Work with animals?                                                                                | <input type="checkbox"/> NO <input type="checkbox"/> YES SPECIES: _____ |
| 7. Have direct contact with research subjects and/or patients?                                       | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 8. Have contact with human samples (i.e. blood, tissue) obtained from research subjects or patients? | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 9. Have access to protected health information (PHI) or personal identifying information (PII)?      | <input type="checkbox"/> NO <input type="checkbox"/> YES                |
| 10. Have access to VA patient information systems (CPRS)?                                            | <input type="checkbox"/> NO <input type="checkbox"/> YES                |

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Print Investigator/Supervisor

Signature Investigator/Supervisor

Date

PLEASE RETURN THIS FORM TO: [Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@va.gov)

**\*NOTE:** Due to the identifiable information on this document, please be sure to **ENCRYPT YOUR E-MAIL** if sending the form electronically. If you are unable to send this form encrypted, please reach out to Zhoie Bigham ([Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@va.gov)) to discuss alternative delivery options.

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For office use only:

☐ WOC      ☐ IPA

TYPE OF PIV ISSUED: ☐ Flashpass ☐ USAccess PIV

## Scope of Practice for Research Personnel

NAME OF RESEARCH PERSONNEL	EMAIL ADDRESS
PRIMARY PRINCIPAL INVESTIGATOR/SUPERVISOR <i>(Form can be signed by multiple PI's when applicable)</i>	ROLE IN RESEARCH <i>(Investigator, Research Staff, Statistician, Consultant, Etc...)</i>
<b>Please indicate type of Employee:</b> <input type="checkbox"/> Study Team Member – VA Employee <input type="checkbox"/> 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 Principal Investigator. 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 principal investigator(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**

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

### **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**

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

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

### **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

\_\_\_\_\_  
Principal Investigator

Date

\_\_\_\_\_  
Principal Investigator (Secondary, not required)

The original signed Scope of Practice will be maintained in the Research Business Office. The Supervisor and/or Principal Investigator 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 second to last block on page 2, 'Operations Support'.





Employee's Name:

Job Title:

Department/Service Assigned:

An Assignment of Functional Category is a classification of an employee by their supervisor indicating their level of access to Individually Identifiable Health Information (IIHI) and/or Protected Health Information (PHI). This form must be completed 1) upon hiring and in-processing; 2) annually thereafter; and 3) as needed due to job changes between annual reviews. Supervisor and employees should have a discussion which clearly communicates the level of access to IIHI/PHI as well as when, and what, employees may access in the performance of their assigned duties. Functional category for medical residents or other health professional trainees is assigned within their MTT training (TMS 3185966 or 3192008). If an employee's duties are covered by 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.

**Immediate Supervisor:** Check off functional category, review with employee, obtain signatures, and maintain copy in the *Supervisor's Personnel Files* (RCS10-1,3000.18) for the individual employee.

	Functional Categories (Class of Persons)	Type of Protected Health Information Accessible	Allowable Systems of Records Notice (SORN) for Limited Access	Primary Conditions for Access to Information
<input type="checkbox"/>	Direct Care Providers (e.g., Licensed Independent Practitioners, Nurse, Chaplain, Psychologist, Pharmacist, Social Worker, Therapists, Dietitian and Health Care Professional Trainees)	Entire Health Record		Treatment of Individuals
<input type="checkbox"/>	Department of Veterans Affairs (VA) Researchers	Entire Health Record (including research records)		Activities as approved by an Institutional Review Board or Privacy Board; Preparatory to Research
<input type="checkbox"/>	Indirect Care Providers (e.g., Pharmacy/Lab/X-ray Technicians and Health Care Professional Trainees)	Entire Health Record		In support of treatment of individuals
<input type="checkbox"/>	Community Care Office Purchased Care Office Administrative Staff	Entire Health Record		In support of Purchased Care Office oversight functions such as payment, reimbursement, income verification and eligibility benefits
<input type="checkbox"/>	Health Information Support Services Staff (e.g., Medical Support Assistants, Health Unit Coordinators, Medical Record Administrators/ Technicians, Release of Information Specialists, Transcriptionists, Billing and Coding Specialists, Tumor Registrars, Enrollment and Eligibility Staff)	Entire Health Record		Assigning diagnostic codes, billing, transcription, filing, scanning, release of information, patient look-up, providing or inputting registry data, insurance and eligibility verification, patient complaints and resolution
<input type="checkbox"/>	Quality, Oversight and Investigations (e.g., Quality Management, Risk Management, Infection Control, Utilization Review, Radiation and Environmental Safety Officers, Peer Reviewers, Narcotic Inspections)	Entire Health Record		Address medical inspections, investigations, complaint review and resolution, quality reviews, patient safety reviews, compliance reviews, and provide congressional responses

	Functional Categories (Class of Persons)	Type of Protected Health Information Accessible	Allowable Systems of Records Notice (SORN) for Limited Access	Primary Conditions for Access to Information
<input type="checkbox"/>	Chief of Police, Assistant Chief of Police Officer	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Performing security related functions that require access to patient contact information. (i.e. parking infractions, warrants, security actions-validating presence on VA grounds, correspondence)
<input type="checkbox"/>	Police Dispatchers	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Performing security related functions that require access to patient contact information. (i.e. parking infractions, warrants, security actions-validating presence on VA grounds, correspondence)
<input type="checkbox"/>	Police and Security Service	Police and Security Service		Law enforcement function
<input type="checkbox"/>	Care-Related Committee Members (Committees such as; Disruptive Behavior, Ethics, Medical Record, Narcotics Review, etc.)	Entire Health Record		Treatment of individuals and health care operations with compliance and charter responsibilities
<input type="checkbox"/>	Occupational Health	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Treatment of employees
<input type="checkbox"/>	Patient Support Positions (e.g., Patient Advocate)	Entire Health Record		Performing Patient Support Operations
<input type="checkbox"/>	Regulatory Support Positions (e.g., Facility Information Systems Security Officers (ISSO), Privacy Officers (POs), Compliance Officers, VISN ISSO, POs and Compliance Officers, Records Managers, Research Compliance Officers, FOIA Officers)	Entire Health Record (including research records)		Monitoring and tracking of security, privacy, patient care and compliance issues
<input type="checkbox"/>	Operations Support (Contracting, Acquisitions, Human Resources, Employee Education, Library, Engineering, Telecommunications)	No need for access to PHI		Internal operations
<input type="checkbox"/>	Facility and VISN Leadership and Management	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Overseeing of operation and management, executive decisions for health care operations

	<b>Functional Categories (Class of Persons)</b>	<b>Type of Protected Health Information Accessible</b>	<b>Allowable Systems of Records Notice (SORN) for Limited Access</b>	<b>Primary Conditions for Access to Information</b>
<input type="checkbox"/>	Administrative Support (MHV Coordinator, Bio-Medical, Administrator Officer of the Day (AOD), Equal Employment Opportunity (EEO), Public Affairs, Call Center Support, Program Support Staff, Mail Room Staff, Food Prep Staff, Union Steward	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Administrative, public, and employee support
<input type="checkbox"/>	Environmental Support Staff (e.g. Groundskeepers, Building Management)	No need for access to PHI		Maintenance of grounds, buildings, and housekeeping
<input type="checkbox"/>	Information Technology (e.g. Clinical Application Coordinators, Automated Data Processing Application Coordinators (ADPACS) OI&T Staff, Decision Support Staff, Area Managers, Chief Medical Information Officers, Chief Health Informatics Officers)	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Maintenance and support of computer systems, as well as, employee computer support
<input type="checkbox"/>	Veterans Canteen Service, Cafeteria, Retail Store	No need for access to PHI		Retail and food services for employees and Veterans
<input type="checkbox"/>	Volunteer Services (e.g., Reception Desk, Facility Escorts, Transportation Drivers)	Limited Health Record (when necessary to complete the task)	Any Privacy Act SORN related to the task	Transportation of patients with vehicles, information desk support and escorting patients to appointments
<input type="checkbox"/>	VHA Program Office, VACO Leadership	Limited Health Record (when necessary to the complete task)	Any Privacy Act SORN related to the task	Overseeing of health care operations, budget and management, executive decisions for VHA Central Office, health care oversight, complaint/inquiry resolution



Employee's Name:

Job Title:

Department/Service Assigned:

## SIGNATURES

**Employee:** By signing this document, I acknowledge my supervisor has explained to me 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 tasks. I will not access, use, or disclose Protected Health Information in any way that does not comply with the Minimum Necessary Standard for Use and Disclosure of Protected Health Information.

**Supervisor:** By signing this document, I attest that I have explained the assigned functional categories and Minimum Necessary Standards for privacy to this employee.

Employee's Signature:

Date:

Supervisor's Signature:

Date:

## ANNUAL REVIEWS

**Note:** A new VA Form 10-0539 must be completed if any changes have been made to the functional category assignments or if there has been a change in duties. If no changes have been made, complete the bottom portion during the employee's annual performance appraisal review.

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

Employee's Signature:

Date:

Supervisor's Signature:

Date:

# 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 Ann Arbor Healthcare System (VAAHS) at Ann Arbor, Michigan, 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 Ann Arbor VA for the purpose of performing research projects, evaluated and approved by the VA Research and Development Committee (VA-approved research), at this location.
2. By signing this agreement, I understand that, except as provided herein, I am adding no employment obligations to the VA beyond those created when I executed the WOC appointment.
3. I have read and understand the VHA Intellectual Property Handbook 1200.18. Available at [https://www.research.va.gov/programs/tech\\_transfer/policies.cfm](https://www.research.va.gov/programs/tech_transfer/policies.cfm), 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 \_\_\_\_\_, 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

\_\_\_\_\_  
WOC Signature

Date

\_\_\_\_\_  
ACOS/R&D Signature

# Research/HSR&D Service Initial Information Form

## -For Human Subjects Research ONLY!

Service will contact the applicant and obtain the following information.  
This information is necessary for Medical Staff/Credentialing Office and Human Resources.

VAAAHS  
2215 Fuller Road 11C  
Ann Arbor, MI 48105

***PLEASE PRINT LEGIBLY***

Full Name: \_\_\_\_\_  
First Middle Last

Title: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
MD, DO, DDS, PhD, PA, NP, etc.

Social Security Number -----

Home Address: \_\_\_\_\_  
\_\_\_\_\_

Email Address: \_\_\_\_\_

Daytime Phone #: \_\_\_\_\_ Fax #: \_\_\_\_\_

Specialty: \_\_\_\_\_

Is the applicant a U.S. Citizen? ☐ Yes ☐ No ☐ Green Card

Is the applicant a ☐ Male ☐ Female?

Applicant will be: ☐ Full Time ☐ Part Time ☐ Consultant ☐ Contract ☐ Fee Basis ☐ MOD ☐ WOC

Target Start Date of Applicant: \_\_\_\_\_

Person completing this form: \_\_\_\_\_ Phone #: \_\_\_\_\_

Service: \_\_\_\_\_ Date: \_\_\_\_\_

**1. Is a required medical degree, license and certification for the practitioner's research position? If so, what?**

**2. Is a Physician/Dentist/PA/NP/CRNA/clinical PhD required to hold that position?** \_\_\_\_\_

**3. Is there clinical patient care?** \_\_\_\_\_

**4. Will he/she be a provider noted on patient records/entering clinical patient information?** \_\_\_\_\_

**\*Note: Please provide the completed IIF to the Credentialing Office: [VHAANN\\_COS\\_Credentialing@va.gov](mailto:VHAANN_COS_Credentialing@va.gov)) to start the credentialing process, if the answer is "yes" to one of the above 1 thru 4 questions.**

***Once Service has completed the Initial Information Form, please forward a copy to:  
Human Resources and Medical Staff Office(if applicable)***

# **Standard Training All Applicants**

## **Instructions for Setting up an IRBnet (VAIRRS) Account**

**All employees working on any VA research projects will be required to set up an IRBnet account that will be used to manage research protocols and upload training certificates.**

**Please visit our website and see the “Creating an Account in VAIRRS” section for how register and set up your IRBnet profile:**

[VA Innovation and Research Review System \(VAIRRS\) - VA Ann Arbor Healthcare System Research Services](#)



The VAAHS requires mandatory training modules (listed below) for every employee to complete annually. Before beginning work as a WOC employee, you must complete at minimum the first three of these modules. If you are involved in either laboratory research or animal research, you will also be required to read documents #4 and #5. 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***
4. ***Chemical Hygiene Plan Training for VAAHS Research*** (Laboratory and Animal Research Only)
5. ***Formaldehyde Training for VAAHS Research*** (Laboratory and Animal Research Only)

The first three modules are accessed via the VA Talent Management System (TMS). This system offers web-based training to VA employees and its partners. For The Chemical Hygiene Plan, please follow this link:

[https://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/Chemical\\_Hygiene.pdf](https://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/Chemical_Hygiene.pdf)

The Formaldehyde Training can be found here:

[https://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/Formaldehyde\\_Training.pdf](https://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/Formaldehyde_Training.pdf)

**Once you have reviewed each document, please sign the certificate at the end and send those to Zhoie Bigham at [Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@va.gov).**

#### **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 Zhoie Bigham at [Zhoie.Bigham@va.gov](mailto:Zhoie.Bigham@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 on the day of your appointment.\*\*\***

## 1. Step-by-Step Instructions

1. From any computer, launch a web browser and navigate to <https://www.tms.va.gov/secureauth35/>
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. **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.
    - ii. Re-enter **Social Security Number**
    - iii. **Date of Birth**
    - iv. **Legal First Name**
    - v. **Legal Last Name**
    - vi. **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.
    - vii. Re-enter **email Address**
    - viii. **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 **Zhoie**
    - v. **VA Point of Contact Last Name** – Enter **Bigham**
    - vi. **VA Point of Contact eMail Address** – Enter **zhoie.bigham@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. To print certificates, 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 (DO NOT CLICK ON THE COURSE). Click on '**Print Completion Certificate**' for all the mandatory training required for the WOC application.

## 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](mailto:VAMSEHelp@gpworldwide.com).**

**\*PLEASE BE SURE TO SAVE A COPY OF ALL TRAINING CERTIFICATES**

**If you will not be participating in Human Subjects Research,  
please skip ahead to your respective research section.**



# **Human Subjects Research Training & Forms**

## VA HUMAN SUBJECTS RESEARCH

All personnel assigned to a human subjects protocol/project 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 Affiliation 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 Institutional 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 = no.
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, Zhoie Bigham  
(Zhoie.Bigham@va.gov), 734-845-5600
2. R&D Coordinator, Brandy Schneider (Brandy.Schneider@va.gov), 734-845-5602
3. Human Studies Coordinators, Cathy Kaczmarek (Catherine.Kaczmarek@va.gov),  
Terry Robinson (Terry.Robinson3@va.gov), or Sheena Hatcher  
(Sheena.Hatcher@va.gov), 734-845-3440

**\*If you will NOT be participating in Laboratory or Animal Research, please stop HERE!**

# **Animal Subjects Research Training & Forms**

## VA ANIMAL SUBJECTS RESEARCH

**All personnel assigned** to animal protocols/projects must complete the following training in the Collaborative Institutional Training Initiative (CITI) at the University of Miami. Additionally, animal research workers must complete the Occupational Health & Safety, Medical Surveillance questionnaire and vaccination record.

**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.

**Working with the IACUC** and **Working with (species) in Research Settings** are required VA research courses that must be completed every three (3) 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 Affiliation 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 Institutional 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 = select "no" unless you are a member of the VA IACUC Committee.
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 = select "yes" if you will be utilizing laboratory animals.
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 people below.

1. WOC Coordinator/Program Support Assistant, Zhoie Bigham  
(Zhoie.Bigham@va.gov), 734-845-5600
2. Animal Studies & Research Safety Coordinator, Carolyn Slusher  
(Carolyn.Slusher@va.gov), 734-222-7981
3. R&D Coordinator, Brandy Schneider (Brandy.Schneider@va.gov),  
734-845-5602



# 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 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...

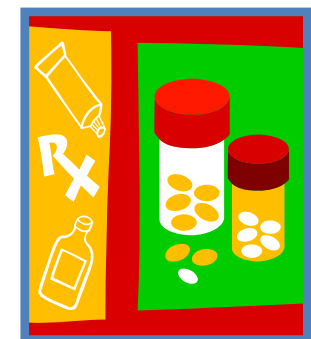
The proper use of hazardous biological, chemical, and physical agents in animals depends on careful planning, proper training, and careful attention to prescribed work practices. Signs should be posted indicating the

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) 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 VAAHS Employee Health personnel.

I participate in the University of Michigan Occupational Health and Safety Program for Personnel Working with Animals.

Name \_\_\_\_\_

Date \_\_\_\_\_

Signature \_\_\_\_\_

Name of Principal Investigator \_\_\_\_\_

## LABORATORY EMPLOYEE SAFETY TRAINING CHECKLIST

Employee Name	Supervisor	WOC <input type="checkbox"/> VA Employee <input type="checkbox"/>	Start Date
---------------	------------	----------------------------------------------------------------------	------------

All Laboratory personnel must complete annual safety training. Complete the items relevant to your lab area with your supervisor. **- This form should be completed AFTER your first day of employment and returned to Zhoie Bigham (Zhoie.Bigham@va.gov)**

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

Employee Signature	Date	Supervisor Signature	Date
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**If you will not be participating in either Human or Animal Research, please skip to Laboratory Section.**



# **Laboratory Training & Forms**

## NEW VA RESEARCH LABORATORY WORKERS

All personnel working in a lab 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 Affiliation 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 Institutional 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 = Select "no" unless you are a member of the VA IACUC Committee.
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 = select "yes" if you will use laboratory animals.
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, Zhoie Bigham  
(Zhoie.Bigham@va.gov), 734-845-5600
2. R&D Coordinator, Brandy Schneider (Brandy.Schneider@va.gov), 734-845-5602
3. Human Studies Coordinators, Cathy Kaczmarek (Catherine.Kaczmarek@va.gov),  
Terry Robinson (Terry.Robinson3@va.gov), or Sheena Hatcher  
(Sheena.Hatcher@va.gov) 734-845-3440
4. Animal Studies & Research Safety Coordinator, Carolyn Slusher  
(Carolyn.Slusher@va.gov), 734-222-7981

## LABORATORY EMPLOYEE SAFETY TRAINING CHECKLIST

Employee Name	Supervisor	<b>WOC VA Employee</b>	Start Date
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All Laboratory personnel must complete annual safety training. Complete the items relevant to your lab area with your supervisor. - **This form should be completed AFTER your first day of employment and returned to Zhoie Bigham (Zhoie.Bigham@va.gov)**

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

Employee Signature	Date	Supervisor Signature	Date
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