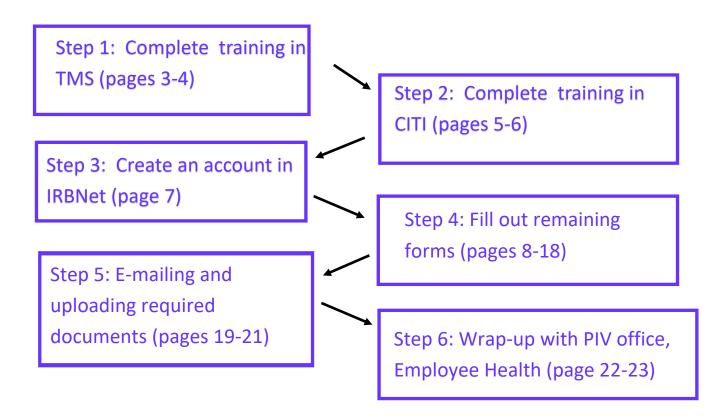


VA Ann Arbor Healthcare System

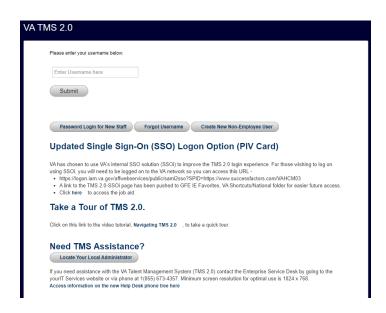
Application for Interpersonnel Agreement (IPA) Detail

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





Step 1: Complete Training in Talent Management System (TMS) 2.0



Before beginning work as a WOC employee, you must complete the modules listed below. You will be required to complete them annually to stay in compliance.

- VA Privacy and Information Security Awareness Training and Rules of Behavior (VA 10176)
- Infection Control: Bloodborne Pathogens and Tuberculosis (VA 12434)
- Government Ethics—The Essentials (VA 3812493)
- Technology Transfer Program Training (VA 131008977)
- VHA Privacy and HIPAA (VA 10203) only required if you conduct human subjects research

Follow the instructions on the next page to register for an account and add training.

Step 1 continued: Complete Training in Talent Management System (TMS) 2.0

- 1. From any computer, go to https://www.tms.va.gov/secureauth35/
- 2. Click "Create New Non-Employee User"
- 3. Select "Veterans Health Administration (VHA)
- 4. Select "WOC (those working for VA without VA compensation)"
- 5. Complete the entries for "My Account Information"
- 6. Under "My Job Information", enter the following:
 - A. VA Location: Click on the blue funnel and search for "ANN"
 - B. VA Point of Contact First Name: Zhoie
 - C. VA Point of Contact Last Name: Bigham
 - D. VA Point of Contact Email Address: Zhoie.Bigham @va.gov
 - E. Point of contact phone number: 734-845-5600
 - F. Check "HIPAA Training Required" if you work with human subjects/data
- 7. Click "Submit". Your profile will be created
- 8. Click on the "Continue" button to load your to-do list of required training
- 9. Complete the content
- 10. To access certificates, click on the "Learning History" section
- 11. Click on the printer icon for the course you are interested in
- 12. Once the certificate appears, you can save it to your computer
- 13. Certain certificates will need to be provided to the WOC coordinator or up-loaded to your IRBNet account (see page 24)

Step 2: Complete Training in CITI

Additional training in the CITI program will be assigned depending on your job duties. Follow the steps below to set up an account:



- 1. From any computer, go to https://about.citiprogram.org
- 2. Click "Register" (Note: If you already have a CITI account, you do not need to create a new one.

 After logging in, select "add affiliation". See step 4)
- 3. Click "Select Your Organization Affiliation"
- 4. Search for "VA Ann Arbor, MI-506"
- 5. Check the boxes and select "Create a CITI Program Account"
- 6. Enter your information and click "Continue to Step 3"
- 7. Create your username, password, and security question then go to step 4
- 8. Fill in the required information for Country of Residence, etc, then go to step 5
- 9. Answer the questions for continuing education until then go to step 6
- 10. Fill in the information then go to step 7
- 11. You will be asked a series of questions. You should select answers that correspond with your role in VA research. See the next page for suggestions and helpful hints.
- 12. After you have answered the questions, select "complete registration"
- 13. Click "Finalize Registration"
- 14. Complete the required coursework and save the completion certificates
- 15. Certain certificates will need to be provided to the WOC coordinator or uploaded to your IRBNet account (see page 24)

Step 2 continued: Complete CITI Training

- Question 1: Check yes if you work with human subjects or human data. You will need to complete "VA Human Subjects Training"
- Question 2: If you answered "yes" to question 1, you may need to select an additional box if you work with investigational drugs or devices or industry-sponsored studies. Check with your PI or supervisor if you are not sure.
- Question 3: Answer "no" to this question as only members of the IACUC need to take this course.
- Question 4: Answer "yes" if you will be working with laboratory animals. You will be assigned "Working with the VA IACUC"
- Question 5: If you answered "yes" to question 4, you must select the species. You will be assigned "Working with {lab animal} in research settings".
- Question 6: This course is optional for lab staff, but highly recommended if you conduct animal research. If you answer "yes", you will be assigned "Postapproval monitoring"
- Question 7: If you answered "yes" to question 4, you must answer question 7.
 If you are conducting rodent survival surgery, check "yes" and you will be assigned "Post Procedure Care of Mice and Rats". Check with your PI/supervisor if you aren't sure.
- Question 8: If you work in a VA laboratory, you must select one of the first two
 answer to have "Introduction to VA Biosecurity Concepts" added.
- Question 9: No answer required. Only applies to members of the R&D committee.
- Question 10 and 11: If you work in a VA laboratory, select "yes" to both questions. You will be assigned "<u>Lab Chemical Safety</u>" and "<u>Formaldehyde</u> Safety Awareness"

Step 3: Create an Account in IRBNet

Continue



IRBNet (sometimes referred to as VAIRRS) is the system we use to provide regulatory oversight of VA research projects and the staff conducting the research.

Create your IRBNet account:

- 1. Go to https://gov.irbnet.org
- 2. Select "Register Now"

Agency network.)

Forgot your Username or Password? Click here for help.

- 3. Fill out your first and last name. Use the drop-down box to select your research institution as "VA Ann Arbor Healthcare System". Choose a username and password and select "Continue"
- 4. Enter remaining information. Click "Register"
- 5. An automated activation email will be sent to you. You will need to click the link within the email to activate your account.

Link your CITI account to IRBNet

- 1. From within IRBNet, select "User Profile" on the upper right side
- 2. Scroll down to External Accounts. Click "Add External Account"
- 3. Enter your associated CITI Member ID from your CITI account. This number can be found at the top of your CITI homepage upon login.
- 4. A verification link will be sent to the email associated with your CITI account.
- 5. After verifying, coursework will be pulled into IRBNet over the next 24 hours and will continue to update automatically.

Step 4: Fill out Remaining Forms

Complete the following forms:

- ⇒ Research Service New Employee Information Sheet (Page 9)
- ⇒ Scope of Practice (Pages 101—113; Requires Applicant and PI signature; WOC coordinator will obtain remaining signature)
- ⇒ Intellectual Property Agreement (Page 14; Requires Applicant signature; WWOC coordinator will obtain remaining signature)
- ⇒ Laboratory Employee Safety Training Checklist (Page 15; Requires Applicant and PI signature; There is an opt-out box to check if you do not conduct any activities in a research laboratory setting)
- ⇒ Occupational Health and Safety Program Explanation and Acknowledgement (Page 16-18; Requires Applicant signature; <u>There is an</u> <u>opt-out box to check on page 161if you do not conduct research</u> <u>involving animals</u>

Research Service New IPA Information Sheet

Employee Nar	me:				
Other Names	Used (Maiden Name	e, Aliases, etc):		
Date of Birth:					
Place of Birth	(city, state, province	, country):			
Social Security	y Number:				
Current Resid	ential Address:				
Cell Phone Nu	ımber:				
Home Phone	Number:				
U.S. Citizen	NO	YE	S		
Gender (as inc	dicated on governme	ent issued ID	: Male		Female
Degree:	University/Pro	gram Attende	ed:		
	Completion Da	te:			
VA Job Title:					
Start Date:					
VA Supervisor	-:				
Work Address	: :				
Work Phone N	Number:				
E-mail addres	s:				
Do you need a	access to Bldg 22 or	31? NC	YES		
Do you need a	a VA computer netw	ork account?	NO		YES
If yes, what ap	oplications will you n	ieed?			
Electronic	Health Record	Remote Ac	cess/VPN	Other	



Scope of Practice for Research Personnel

NAME OF RESEARCH PERSONNEL	EMAIL ADDRESS
PRIMARY PRINCIPAL INVESTIGATOR OR SUPERVISOR	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. <u>RESEARCH TEAM MEMBERS</u>: The Scope of Practice is specific to the duties and responsibilities of Research Personnel (Employee or WOC or IPA) 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. <u>PRINCIPAL INVESTIGATORS</u>: 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.
П	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 I HUMAN SUBJECT RESEARCH

Routine Duties	YES	NO
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.		
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.		
16. Other (i.e. project consulting, please detail below in "Miscellaneous Duties)		
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 specified in this Scope of Practice. 1. 2.	us duties no	t otherwise

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)		
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)		
9. Other (please detail in "Miscellaneous Duties" below).		
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.		
	\\	110
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).		
Orders laboratory animals.		
4. Other (please detail in "Miscellaneous Duties" below).		
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 specified in this Scope of Practice. 1.	us duties no	t otherwise
2.		

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 or Supervisor	Date
The original signed Scope of Practice will be mai Office. Research personnel should upload a copy Principal Investigator should also maintain a copy any regulatory binders.	• •
OFFICE LISE ONLY.	
OFFICE USE ONLY:	
ACOS/Research & Development Service	Date

VA – IPA APPOINTEE INTELLECTUAL PROPERTY AGREEMENT

in consi Healtho	deration of my Intergovernment	and the Department of Veterans Affairs (VA) all Personnel Act (IPA) appointment by the VA Ann Arbor arbor, Michigan, and performing VA-approved research (as defined
1.		ne Ann Arbor VA for the purpose of performing research projects, evaluated ch and Development Committee (VA-approved research), at this location.
2.		derstand that, except as provided herein, I am adding no employment ose created when I executed the IPA appointment.
3.	https://www.research.va.gov/p	VHA Intellectual Property Handbook 1200.18. Available at rograms/tech_transfer/policies.cfm, which provides guidance and disclosures, patenting and the transfer of new scientific discoveries.
4.	to VA any invention that I make	mployee or appointee at, I will disclose while acting within my VA-IPA appointment in the performance of VA-resources at the VAMC or in VA-approved space.
5.	decide whether VA can and will within 40 days of receipt of a co contribution to the invention, to	of General Counsel (OGC) will review the invention disclosure and will assert an ownership interest. Every effort will be made to issue a decision mplete file. OGC will base its decision on whether VA has made a significant o include my use of VA facilities, VA equipment, VA materials, VA supplies, sessment of the potential of the invention.
6.	I agree to assign certain owners VA, when requested, in drafting	rest based on my inventive contribution, then, subject to Paragraph 7 below, hip rights I may have in such invention to the VA. I agree to cooperate with 3 the patent applications(s) for such invention and will thereafter sign any wnership, as required by the U.S. Patent and Trademark Office at the time
7.	disclose and assign certain inve	red or appointed at the entity named in paragraph 4 and have obligations to ention rights to it. If that entity asserts an ownership interest, VA will development of the invention as appropriate.
8.		greement (IMA) exists between the VA and the mentioned entity in ll be implemented in accordance with the provisions of that IMA.
		I IPA Signature
		ACOS/R&D Signature

VAAAHS Research Service (151)

LABORATORY EMPLOYEE SAFETY TRAINING CHECKLIST

Employee Name	Supervisor	IPA VA Employee	Start Date
		Tr. Limpley Go	

If you do not conduct any research activities in a laboratory, you can check this box and skip this form.

· ·	
1. Location and <i>use</i> of Life Safety Equipment	SDS Sheets (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)
Showers, Eye Washes (location, use, C. 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 of Operations Plan (EOP) & Continuity of Operations Plan (COOP)
e. Safety equipment specific to your lab, including personal protection equipment (PPE) 1. Lab coats 2. Eye, Face, Hand, Foot, Head	Operation of equipment (such as sterilizers and centrifuges) a. Location of operation Manual b. Documented User Training
Medical Center Safety Policies Manual (review location & check documentation that each person who works in the lab has reviewed manual)	11. Safety of Personnel Engaged In Research VHA Directive 1200.08
3. VA Research Safety Policies On-Line http://www.annarbor.research.va.gov/ ANNARBORRESEARCH/policies.asp	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 FACE DISCIPLINARY ACTION

Employee Signature	Date	Supervisor Signature	Date

If you do not conduct any animal research activities, you can check this box and skip pages 21 - 23.

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 <u>must</u> 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.

16

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...



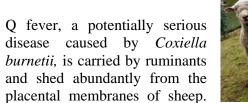
The main risks associated with working with dogs and cats are bites and scratches. Sometimes scratches or bites can result in infections. Cat bites can result in particularly severe

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...





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 <u>MUST</u> 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.

Name 	Date
Signature	Name of Principal Investigator

Step 5: Emailing and Uploading Required Documents



Congratulations on completing the training and paperwork! Follow the flow chart below to ensure the documents are shared and/or uploaded appropriately.

BLUE = EVERYONE

GREEN = HUMAN SUBJECTS

ORANGE—ANIMAL/LABORATORY

	E-mail:	Upload to
	Zhoie.Bigham@va.gov	IRBNet account
TMS Certificate: VA Privacy and Information Security Awareness Training & Rules of Behavior	X	X*
TMS Certificate: Infection Control: Bloodborne Pathogens and Tuberculosis	X	X*
TMS Certificate: Technology Transfer Program	X	
TMS Certificate: VHA Privacy and HIPAA	X	X*
CITI Certificate: VA Human Subjects	X	X**
CITI Certificate: Working with the VA IACUC	X	X**
CITI Certificate: Working with {lab animal} in research settings	X	X**
CITI Certificate: Introduction to VA Biosecurity	X	X**
CITI Certificate: Lab Chemical Safety and Formaledehyde Safety Awareness		X**

^{*}See page 21 for instructions on uploading documents to IRBNet

^{**}If you link your CITI account to IRBNet, training will automatically be added and you will not need to upload to IRBNet.

Step 5 Continued: Emailing and Uploading Required Documents

E-mail: Upload to Zhoie.Bigham@va.gov IRBNet account

Research Service New Employee Information Sheet	X*	
Scope of Practice	X*	X**
Intellectual Property Agreement	X*	X**
Laboratory Employee Safety Training Checklist	X*	
Occupational Health and Safety Acknowledgement	X*	

^{*}These forms are already part of a single PDF. You can email the entire booklet to Zhoie. Since there is sensitive, personal information, be sure to encrypt the email. Contact Zhoie if you would like to discuss alternate methods.

^{**}The forms require Associate Chief of Staff signature. The research office will obtain the signature and upload to your IRBNet account and also return signed forms to you.

Step 5 Continued: Emailing and Uploading Required Documents



Adding training to your IRBNet account:

- 1. Go to https://gov.irbnet.org
- 2. Select "User Profile" on the upper right side of the screen
- 3. Scroll down until you get to the "Training and Credentials" section
- 4. Select "Add a New Training & Credentials Record"
- 5. Select a choice from the drop down menu
- 6. Attach the training certificate or document
- 7. Enter the date the training was completed and the expiration date. TMS training is only good for one year.

Step 6: Wrap-Up with PIV Office, Employee Health, Etc.



- Depending on your job duties, you may need health clearance from employee health. You will receive an email from HR with instructions on how to make an appointment. You will also need to fill out an Animal Contact Questionnaire (if applicable) and an Immunization Record. These forms can be found <u>HERE</u>. Fill them out, print them, and take them with you to your appointment.
- A background check may be emailed to you through eQIP which will need to be completed. Instructions will be provided in the email.
- After emailing your packet to Zhoie, you will receive instructions to set up an
 appointment with the PIV office for finger-printing. You will need to take two
 forms of identification to this appointment (see the next page for acceptable
 documents)
- For research building access (bldg 31 or 22), email Zhoie.Bigham@va.gov.
 Zhoie will send you a memo by email. Take your PIV card and the memo to
 CB08 (main hospital basement) to have your access turned on.
- Please remember that even after being cleared by the research office, you
 may not begin work on VA research until your PI/Supervisor has received an
 approved staff change request through IRBNet.

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
 A U.S. Passport or U.S. Passport Card A Permanent Resident Card or Alien Registration Receipt Card (Form I-551) A foreign passport An Employment Authorization Document that contains a photograph (Form I-766) A Driver's license or ID card issued by a State or possession of the United States provided it contains a photograph A U.S. Military card A U.S. Military dependent's ID card A PIV Card 	 A U.S. Social Security Card issued by the Social Security Administration 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 An ID card issued by a federal, state, or local government agency or entity, provided it contains a photograph A voter's registration card A U.S. Coast Guard Merchant Mariner Card A Certificate of U.S. Citizenship (Form N-560 or N-561) A Certificate of Naturalization (Form N-550 or N-570) A U.S. Citizen ID Card (Form I-197) An Identification Card for Use of Resident Citizen in the United States (Form I-179) A Certification of Birth Abroad or Certification of Report of Birth issued by the Department of State (Form FS-545 or Form DS-1350) A Temporary Resident Card (Form I-688) An Employment Authorization Card (Form I-688A) A Reentry Permit (Form I-327) A Refugee Travel Document (Form I-571) An Employment authorization document issued by Department of Homeland Security (DHS) An Employment Authorization Document issued by DHS with photograph (Form I-688B) A driver's license issued by a Canadian government entity
Updated 3/28/16 23	A Native American tribal document

Leaving the VA?



IPA appointments need to be <u>renewed every 4 years</u>. If you leave prior to the end of your 4 year term, please be sure to do the following:

- Have your PI/supervisor submit a staff change form to remove you from their projects
- Turn in your PIV badge to the PIV office
- Send an email to Zhoie. Bigham@va.gov informing her of your last day.