

October 16, 2012

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)
ANIMAL AND LABORATORY
Training & Research Clearance**

1. **PURPOSE:** All individuals involved in animal and laboratory research must receive the training necessary to ensure research is carried out in the prescribed manner and is consistent with VA and Federal regulations. Purpose of this policy is to standardize the process for obtaining research clearance. This policy applies to all new and current research personnel participating in Research and Development approved projects. Principal investigators (PI) are central to assisting their personnel in obtaining clearance to conduct research activities. Verification of education and licensure, training to include Collaborative Institute Training Initiative (CITI) and Talent Management System (TMS) specified courses, and completion of affiliation documentation is required prior to conducting research activities.

2. **POLICY:** Principal investigators, research assistants, husbandry staff and IACUC members are required to complete appropriate duty specific training as outline below. In addition, all personnel conducting research activities must have an approved research appointment and a scope of work.

3. **ACTION:**

a. **REQUIRED TRAINING:**

(1) **Investigators and research personnel conducting animal research** – must complete the VA CITI course entitled “Working with the VA IACUC”, all species-specific web courses that relate to animals used in their research project and post procedure training, if applicable. In addition, all new research study personnel since April 2007 must complete CITI course entitled “Biosecurity” training if they will perform their work within VA Facilities. All courses are found at <http://www.citiprogram.org>. See Attachment 1.

(2) **Investigators and research personnel conducting laboratory studies** – must complete the VA CITI course entitled “Biosecurity” found at <http://www.citiprogram.org>. See attachment 1.

(3) **IACUC members** – must successfully pass the Essentials of the IACUC for Members course examination found at <http://www.citiprogram.org>. See attachment 1.

(4) **Veterinary Medical Unit husbandry staff** – The Veterinary Medical Unit (VMU) supervisor determines appropriate training courses for VMU staff. Courses may include those on the CITI web site <http://www.citiprogram.org> and the American Association for Laboratory Animal Science web-based training developed for them at www.aalaslearninglibrary.org. All VMU husbandry staff have been provided AALAS learning library authorization access for courses leading to possible AALAS certification..

b. **ADDITIONAL TRAINING:**

(1) **Talent Management System:** Investigators and research personnel must complete Information Security 201, Information Security Awareness and Rules of Behavior, and Privacy and HIPAA found at <https://www.tms.va.gov/>. See attachment 2.

(2) **VMU Orientation Training:** The VMU Supervisor ensures orientation training for new research personnel working in the VMU. This training includes safety procedures, a review of VMU standard operating procedures and a tour of the VMU facilities.

c. **OCCUPATIONAL HEALTH BASELINE AND CERTIFICATION:** Animal researchers must complete the occupational health questionnaire and certification. Personnel working on-site make an appointment with the VA Occupational Health physician and take the documents with them for certification. If conducting research off site at UTHSCSA, researchers must complete the same occupational health questionnaire and certification; however, they make an appointment through the UTHSCSA Employee Health Clinic for certification. NOTE: Personnel listed on animal protocols, not participating in hands-on animal research, are not required to complete the occupational health questionnaire or certification.

d. **VERIFICATION AND TRACKING:**

(1) **New Protocol Submission:** As part of a new protocol submission, the PI will provide a personnel list. A fillable personnel list/form is available on <http://www.southtexas.va.gov/Research/Protocol.asp> for download. The IACUC Administrator will compare the personnel list against the ACORP personnel list for consistency before forwarding to the Personnel Coordinator for verification using the Research Personnel Database for appropriate VA affiliation, training, and required documents. The Research Office will check the training database and documentation to ensure all personnel listed have completed the required training. Final R&D Committee approval will not be given until training for the PI has been confirmed. Only personnel who have current training at the time of approval will be allowed to participate in the activities related to the protocol.

(2) **Annual continuing reviews:** PIs must fill-in all columns to the right of the researchers' name on the first page. The IACUC Administrator will verify all personnel on the continuing review document are consistent with the approved ACORP. The administrator will provide the Personnel Administrative Assistant with the active personnel list for verification using the Research Personnel Database for appropriate VA affiliation, training, and required documents. Following verification, the administrator will communicate with the PI the status of study personnel, if delinquent. Study personnel who are delinquent on their CITI trainings will be notified that they cannot participate in project related activities until personnel have met training requirements. If the PI is not current on his/her CITI training, the protocol will be placed on administrative hold and the protocol approval will expire.

(3) **Modification Submission:** Should the modification include personnel additions or deletions, the principal investigator will include the personnel list/form available at <http://www.southtexas.va.gov/Research/Protocol.asp> for download. The IACUC Administrator will compare the information provided against the approved ACORP. If certain particulars during the review are inconsistent, the administrator will resolve the inconsistency with the principal investigator before forwarding the personnel list to the Personnel Coordinator for verification using the Research Personnel Database for appropriate VA affiliation, training, and required documents.

(4) **Verification:** Training will be verified through CITI and TMS databases. It is suggested that investigators and research personnel print CITI completion certificates to serve as documentation in the event of an electronic database failure.

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e. **FREQUENCY:** R&D office will verify biennial animal training completion, and one time Biosecurity training, prior to JIT, Secondary JIT, Continuing Review, or Third Year Review approval.

4. **REFERENCES:** VHA Handbook 1200.07

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RESCISSIONS:** Research Memorandum 11-13, August 23, 2011

7. **RECERTIFICATION:** October 2017


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Attachments 2:

1. CITI Instructions
2. Talent Management System Instructions

ATTACHMENT 1

COLLABORATIVE INSTITUTE TRAINING INITIATIVE

WHO: All individuals involved in animal research studies must complete the mandatory training bi-annually

WHAT: All investigators/staff must complete the VA web-based training (1) “Working with the IACUC” specific animal species training. The UTHSCSA CITI training equivalents are acceptable for off-site research personnel. Biosecurity training is required for all research investigators regardless of work location and personnel working on VA premises.

DOCUMENTATION:

- (1) A Certificate of Completion can be printed upon completion of the course.
- (2) The IACUC Administrator will maintain an Access database for tracking of training requirements.

WHEN: All training must be completed prior to participation in a VA-approved animal or laboratory research study and on or before the biennial anniversary. New project approvals and continuing review re-approvals will require that all project staff complete the training within the previous 24 months.

PROCEDURES FOR COMPLETING THE VA WEB-BASED ANIMAL COURSES

1. Location: <http://www.citiprogram.org>

Courses:

IACUC Members: *“Essentials for IACUC Members”*

Investigators/staff: *“Working with the VA IACUC” plus the following that apply to the research:*
“Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress”
“Working with Guinea Pigs in Research Settings”
“Working with Hamsters in Research Settings”
“Working with Mice in Research Settings”
“Working with Rabbits in Research Settings”
“Working with Rats in Research Settings”
“Biosecurity (Note: This applies to all principal investigators regardless of site location and their personnel working on VA premises)”
(Courses for other species are also available)

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ATTACHMENT 2

TALENT MANAGEMENT SYSTEM (TMS)

This is the national website to the TMS: <https://www.tms.va.gov/> . From this site staff can access the training curriculum.

It is very important to ensure "desktop configuration settings" are correct on PC's prior to taking any courses in the TMS. If using a VA Computer, IT can validate proper desktop settings. If using a non-VA computer, setting the desktop is critical. Here is the link to desktop setting instructions: <http://www.insidetms.va.gov/> If these settings are not correct, some courses may not launch properly or record completed learning. Besides logging in for the first time, the biggest problem users' encounter is not being able to access courses due to wrong desktop settings.

Hard copies of the instructions are also on the wall rack located outside of Education Service on Unit 3D along with <http://www.insidetms.va.gov/> pamphlets.

In addition, Education Service has given access to the TMS administrator privileges to the Research Office for its personnel only. They can assist Research Service users with unlocking their TMS accounts, resetting passwords and running training reports.