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

I. **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 (Pl) 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 outlined 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 CIT! 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 must complete CIT! 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 (AALAS) 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 Awareness and Rules of Behavior, and Privacy and HIPAA courses. Investigators must also complete Tech transfer program. 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 provided to them by the Research Service office. Personnel working on-site will make an appointment with the VA Occupational Health physician and take the documents with them for certification. If conducting research off site at UTHSA, researchers must complete the same occupational health questionnaire and certification; however, they make an appointment through the UTHSA Employee Health and Wellness Center 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:**

(l)   **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 it 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:** Pi's must complete the personnel list on the first page of the continuing review document. The IACUC Administrator will verify all personnel on the continuing review document are consistent with the approved ACORP. The administrator will provide the Personnel Coordinator with the active personnel list for verification using the Research Personnel Database for appropriate VA affiliation, training, and required documents. The IACUC 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 till the training is completed.

(3) **Modification Submission:** Should the modification include personnel additions or deletions, the IACUC Administrator will forward the information 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.

e.   **FREQUENCY:** R&D office will verify required CITI and TMS training, and one-time Biosecurity training, prior to 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 12-13, October 16, 2012

7. RECERTIFICATION: March 11, 2024

[Signature on File]

JACQUELINE A. PUGH, MD
ACOS for Research & Development

Attachments:
1. CITI Training Instructions
2. TMS Training Instructions

RESEARCH SERVICE POLICY MEMORANDUM 19-13

COLLABORATIVE INSTITUTE TRAINING INITIATIVE (CITI)

WHO: All individuals involved in animal research studies must complete the mandatory training every three years.

WHAT: All investigators/staff must complete the VA web-based training (I) "Working with the IACUC" and specific animal species training. Biosecurity training is required for all research investigators.

DOCUMENTATION:
        (1) A Certificate of Completion can be printed upon completion of the course.
        (2) The Personnel Coordinator tracks and verifies the training in CITI.

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'* <u>plus</u> the following that apply to their research:
                          "Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress"
                          "Working with Mice in Research Settings"
                          "Working with Rats in Research Settings"
                          "Biosecurity"
                          (Courses for other species are also available)

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.

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