DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78229

Policy Memorandum 23-29
January 5, 2023

RESEARCH STANDARD OPERATING PROCEDURES
Training for Research Involving Human Subjects

1. PURPOSE: All individuals involved in human research must receive the training necessary to ensure human research is carried out in an ethical and safe manner. The purpose of this policy is to identify individuals, for whom human research education is required, the training that will satisfy this requirement, and the procedures for confirming that individuals have met the training requirements.

2. POLICY: Individuals involved in human research studies will be required to receive appropriate training in the ethical principles and accepted practices for the conduct of human subjects' research. This training meets the VA and Federal requirements for human research training.

3. ACTION:

a. The following individuals are required to complete the designated training in the ethical principles of human research protection. Initial training (Basic Course) – learners must complete two (2) required Ethics Modules selected by ORD, plus 6 additional modules from a selected list of 16 elective modules. Refresher Training (Refresher Course) – learners must complete two (2) required ethics modules selected by ORD, plus 6 additional modules from a selected list of 30 elective modules.

(1) All investigators and their research staff involved in research studies involving human subjects.

(2) Members of the Research Office managing human subject research protocols

(3) Members of the R&D Committee

Note: Some programs (e.g. Cooperative Studies Program) may need additional training.

b. Course:

(1) The VA has made available an on-line course that effectively communicates the ethical principles and acceptable practices for human subject's research. Completion of this course satisfies the VA human research training requirement. Current instructions for taking the CITI Course in the Protection of Human Research are provided by the training managers and can be found under Forms and Templates (README_Training Documentation and Credentials Guide) in IRBNet.

(2) Frequency: All individuals must complete this training every three (3) years.

(3) Documentation: Upon completion of the course, individuals should email their certificate of completion to the Research Office and upload a copy in IRBNet under the Track Training Tools.

(4) Tracking: The Research Office will print and maintain a copy of all training certificates in their research privileges folder. A database of current training dates will be maintained to track training compliance. Current training status will be verified at the time of protocol submission and at the time of continuing review.

a. New Protocol Submission: The principal investigator is required to submit a list of all investigators and research staff participating in the project and documentation of their training. 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 has been confirmed for all individuals listed on the project.

b. Continuing Review: At the time of continuing review (annually), the Research Office will verify that training is current for all personnel listed and will contact the person delinquent and their Principal Investigator if any personnel lack current training. Only personnel who have current training will be allowed to participate in the activities related to the protocol. Continued approval will not be given, and approval of the protocol will be suspended if the Principal Investigator does not provide documentation of current training.

c. Non-project personnel: The Research Office will maintain a record of the dates of training for Research Office staff and R&D Committee members. The Administrative Officer or his designee will, at least quarterly, review the training data to initiate reminders to staff and R&D Committee members when training will be due and follow up to ensure training is completed.

d. Other Federal requirements: U.S. Department of Health and Human Services for Human Research Protections (HHS-OHRP) requires that responsible institutional officials be familiar with the VHA Directive 1058.03 and other requirements as stated at Federalwide Assurance (FWA) Registration Instructions - Office of Research Oversight (va.gov) prior to filing/updating a Federal-Wide Assurance (FWA).

4. REFERENCES: Office of Research Protections, Policy, and Education (va.gov); Federalwide Assurance (FWA) Registration Instructions - Office of Research Oversight (va.gov)

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

6. RESCISSION: Research Service Policy Memorandum 18-29, dated April 5, 2018

7. RECERTIFICATION: January 5, 2028

[Signature on File]

Amrita Kamat, PhD
ACOS for Research and Development