SUBJECT: Required Research Training

1. PURPOSE:

To ensure that all personnel engaged in research at the Minneapolis VAHCS have received training that will enable them to perform their duties in an ethical and safe manner and in accordance with regulatory requirements.

2. DEFINITIONS:

MVAHCS: Minneapolis VA Health Care System
RDC: Research and Development Committee
ACOS/R: Associate Chief of Staff for Research
WOC: Without Compensation
IRB: Institutional Review Board
IACUC: Institutional Animal Care and Use Committee
SRS: Subcommittee for Research Safety

3. OVERVIEW:

All MVAHCS research personnel (including WOCs), the Chief of Staff, the Research Compliance Officers, and the members (both voting and ex officio) of the RDC and all its subcommittees are required to undergo periodic training in accordance with the handbooks referenced below, Section 8. The requirements as of the date of this document are outlined in Appendix A. It is the responsibility of the employee to make sure that his/her training is complete and up to date. It is the responsibility of the RDC and its subcommittees to ensure that all personnel participating in VA research are compliant with training requirements. This document outlines the processes the Research Office will implement to facilitate compliance with these requirements.

4. TRAINING DATABASE:

The MVAHCS Research Office will maintain a database that includes, for each individual engaged in research at MVAHCS, the required training elements for all research staff, the most recent completion dates for these trainings, and the next due date for each required training element. This database will be updated on a regular basis, at least once a month. Reports will also be generated on a regular basis to facilitate compliance monitoring (section 5 below).

The RDC and its subcommittees will separately track and record dates of completion for additional training required by individuals participating in specific research protocols. These additional training requirements, including but not limited to human or animal subjects and laboratory safety training, will be reviewed by the RDC or appropriate RDC subcommittee during protocol initiation, renewal, and/or annual protocol review.

5. MONITORING COMPLIANCE:

To ensure that no lapses in training occur, automated reminders will be sent to employees on a regular basis by the training systems used (CITI, TMS). Training lapses will be periodically audited by Research administrative and oversight staff. If lapses in excess of 30 days are identified, the Deputy ACOS/R will notify the individual and his/her direct supervisor. Lapses that are not corrected within one week of notification will be referred to the committee(s) for action, which may include removal of the individual from all affected protocols. Individuals removed administratively may be added back via amendment once training is complete.

6. AUDITS:

Deficiencies in training identified by the Research Compliance Officers during audits will be reported to the applicable research oversight committee.

7. RESPONSIBILITIES:

a) **The ACOS/R** is responsible for developing and managing the policies and procedures that ensure compliance with all educational requirements.

b) **The Deputy ACOS/R** is responsible for ensuring that the database and the compliance monitoring are implemented as described above.

c) **The RDC** is responsible for reviewing and approving this document and assuring training requirements have been met by all research personnel before approving a research study that is not reviewed by any subcommittees (RDC-only protocols).

d) **RDC subcommittees (IRB, IACUC, SRS)** are responsible for ensuring that training requirements have been met before approving a research study. The coordinators of the RDC and its subcommittees are responsible for providing committee-specific training for members and chairs.

e) **The Research Compliance Officers** are responsible for:

i) Advising committee and subcommittee members, ACOS/R and others about state, VA and other federal regulations as needed to ensure compliance; and

ii) Reporting training deficiencies identified in audits to the ACOS/R, the RDC, and appropriate subcommittees.

f) **Principal Investigators** are responsible for:

i) Submitting documentation of successful completion of educational requirements, initially and as required thereafter to the Research Office; and

ii) Ensuring that all individuals involved in their studies have completed all required training.

g) **Research personnel** are responsible for**:**

i) Ensuring that current contact information is registered for Research Office and automated training systems (e.g. TMS or CITI) communications so that messages regarding training requirements are received; and

ii) Responding to requests to initiate or update required training in a timely manner, including completion of all required training prior to participation in a research study.

8. REFERENCES:

VHA Directive 1200.01 “Research and Development Committee” (24 January 2019)

VHA Directive 1200.02 “Research Business Operations” (10 March 2017)

VHA Directive 1200.05 “Requirements for the Protection of Human Subjects in Research” (07 January 2019)

VHA Directive 1200.07 “VA Research with Animals” (23 May 2023)

VHA Directive 1200.08 "Safety of Personnel and Security of Laboratories Involved in VA Research" (24 April 2019)

9. **R & D Committee approval date:** 02 April 2024

10. **RESCISSIONS:** Minneapolis Research Service SOP R&D-010 "Required Research Training" (06 June 2023).

11. **EXPIRATION DATE:** N/A

12. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee

Appendix A: MVAHCS Research Training Requirements

Members of the MVAHCS research community are required to complete a series of training courses. This document outlines these specific training requirements as they relate to:

1) All Research Staff
2) Research Staff involved with Human Subjects Research
3) Research Staff involved with Animal Research
4) Research Laboratory Staff
5) Research Staff working with Safety Hazards
6) Research Committee Members

The MVAHCS Research Office requires that all research staff satisfy training requirements before beginning any research-related activities. Most courses must be renewed periodically.

Please contact the Research Office at VHAMINResearchOffice@va.gov or 612-467-2800 if additional information is needed.

TRAINING REQUIREMENTS FOR ALL RESEARCH STAFF

The following Talent Management System (TMS) courses are required for all MVAHCS research staff on an annual basis:

- *10176 VA Privacy and Information Security Awareness and Rules of Behavior*
  OR *3185966 VHA Mandatory Training for Trainees*
  OR *3192008 VHA Mandatory Training for Trainees – Refresher*
  OR *20152 Mandatory Training for Transient Clinical Staff (Non-Trainees)*
- *131008977 VA Technology Transfer Program Training*

In addition, all staff serving in an investigator role (in any capacity, including Principal Investigator, Co-Principal Investigator, Co-Investigator, etc.) must also annually complete:

- *3812493 Government Ethics – The Essentials*
  OR *3185966 VHA Mandatory Training for Trainees*
  OR *3192008 VHA Mandatory Training for Trainees – Refresher*

Course information can be accessed at: https://www.tms.va.gov/SecureAuth35/

HUMAN SUBJECTS RESEARCH TRAINING REQUIREMENTS

All members of the MVAHCS research community involved in human subjects research, including but not limited to investigators, research coordinators, research assistants, Research Office staff, and IRB administrative staff must complete the following training prior to beginning work with Human Subjects and every three years thereafter:

- *VA Human Subjects Protection*

Course information can be accessed at https://www.citiprogram.org

The following Talent Management System (TMS) course is required on an annual basis for all MVAHCS research staff with direct access to PHI or access to PHI through VA computer systems:

- *10203 Privacy and HIPAA Training*

Appendix A: MVAHCS Research Training Requirements

RESEARCH SAFETY TRAINING REQUIREMENTS

Safety training requirements and links to training materials are provided in:

- Research Safety Training Checklist for Laboratory Personnel
- Research Safety Training Checklist for Non-Laboratory Personnel

Before access to secure research areas will be granted, research staff must complete:

- *VA Biosecurity* - Course information can be accessed at: https://www.citiprogram.org

ANIMAL RESEARCH TRAINING REQUIREMENTS

This section details the requirements for individuals who utilize laboratory animals for research, training, or teaching and:

- Conduct or supervise use of animals on VA property
- Conduct or supervise use of animals purchased with VA funds;
- Conduct or supervise use of animals while on a VA tour of duty but not on VA property

All members of the MVAHCS research community involved in animal research must complete the following training prior to beginning work with animals and every three years thereafter:

- *Working with the VA IACUC*
- *Animal-Specific Training:* The specific courses required related to animal research are dependent upon the role of the staff member and the particular type of animal research being conducted:

ANIMAL POPULATION	COURSE
Mouse	*Working with Mice in Research Settings*
Rat	*Working with Rats in Research Settings*
Hamster	*Working with Hamsters in Research Settings*
Gerbil	*Working with Gerbils in Research Settings*
Guinea Pig	*Working with Guinea Pigs in Research Settings*
Rabbit	*Working with Rabbits in Research Settings*
Swine	*Working with Swine in Research Settings*
Sheep	*Working with Sheep in Research Settings*
Amphibian	*Working with Amphibians in Research Settings*

Course information can be accessed at https://www.citiprogram.org

Appendix A: MVAHCS Research Training Requirements

RESEARCH COMMITTEE MEMBER TRAINING REQUIREMENTS

Members of the **Research & Development Committee (RDC)** or **Institutional Review Board (IRB)** must complete this training at the time of appointment and every three years thereafter:

- *VA Human Subjects Protection*

Members of the **Institutional Animal Care and Use Committee (IACUC)** must complete this training at the time of appointment and every three years thereafter:

- *Essentials for IACUC Members*

Course information can be accessed at https://www.citiprogram.org