SUBJECT: MVAHCS Research Investigator Responsibilities

1. PURPOSE:

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. This SOP outlines the responsibilities of research investigators at MVAHCS.

2. DEFINITIONS:

Research: Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalized knowledge.

VA Research: VA research is research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

VA Investigator: A VA investigator is an individual who conducts research approved by the VA Research & Development committee (RDC) while acting under a VA appointment, including full and part-time employees, trainees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the IPA of 1970. VA investigators must uphold professional and ethical standards and practices and must comply with all applicable VA and VHA and federal regulations and policies.

Principal Investigator (PI): The PI is an investigator in charge of a research project or program. The PI must hold a current paid VA appointment at the Minneapolis VAHCS with a set tour of duty (i.e., not an intermittent VA employee, WOC employee, fee-basis physician, or contracted employee). Trainees can serve as a co- or sub-investigator but must have a VA PI sufficiently experienced in the area of the trainee's research interest to serve as PI. The PI oversees scientific and technical aspects of a grant or protocol and the day-to-day management of the research. For an investigation conducted by a team of individuals, the PI is the responsible leader of that team. Research projects must have a single PI as point of contact. Studies funded by the VA Office of Research and Development (VA-ORD) in which a "Multiple PI" form was filed and accepted by VA-ORD may name both PIs. While multiple PIs are accepted if approved, the VA-ORD does not recognize "Co-PI" as a valid role within VA. For non-VA grants listing an individual as "Co-PI", administrative oversight of the project remains the sole responsibility of the PI. Exceptions to the guidelines listed here for PI roles may be granted by the ACOS on an individual basis except in cases where approval would constitute deviation from published VHA Handbooks or Directives.

Site PI: For studies that include multiple performance sites, a contact PI (Site PI) must be named at the Minneapolis VAHCS. S/he will be responsible for all aspects of the project that occur at the Minneapolis VAHCS including coordination with the overall lead PI and/or other Site PIs. PI eligibility requirements and responsibilities outlined in this document shall apply to any named Minneapolis VAHCS Site PI.

Contract Employee: For the purposes of this SOP, a contract employee is an individual employed through a contract specific to the conduct of research.

3. INVESTIGATOR RESPONSIBILITIES:

Investigators are responsible for:

a) Ensuring that all VA research for which they serve as an investigator meets all VA requirements for the appropriate, safe, and ethical conduct of research. This includes adherence to all applicable VHA handbooks and directives and MVAHCS policies, procedures, and Standard Operating Procedures as they relate to the specific research projects.

b) Ensuring that all personnel participating on research projects for which they serve as principal investigator meet all personnel and training requirements regardless of whether they are VA paid, WOCs, IPAs or contract employees; that they are qualified to perform their research-related tasks; and that they have a current scope of practice on file in the Research Office.

c) Developing and/or implementing a research plan that is scientifically valid; minimizes risk to human subjects, animals used in research, and personnel; and contains a sufficient description of the research including all procedures and the plan for statistical analysis, to allow the RDC and its subcommittees to fully review the research project.

d) Ensuring that all research projects have been reviewed and approved by the RDC and all appropriate subcommittees. The subcommittees of the RDC that may review and approve studies include the Institutional Review Board (IRB) for human studies, the Institutional Animal Care and Use Committee (IACUC) for animal studies, and the Subcommittee for Research Safety (SRS) for studies that involve hazards to research personnel. The RDC serves as the review committee of record for all studies that do not fall under the purview of a subcommittee.

e) Initiating a research study ONLY after receipt of written notification from the Associate Chief of Staff for R&D (The Authorization to Conduct Research form, aka ACR).

f) Obtaining continuing review and approval at a frequency established by the subcommittee, including submission of all materials required for continuing review in sufficient time to assure approval prior to the expiration date. No research activities may be conducted at any time without a currently valid approval.

g) Ensuring that personnel do not work on any research prior to that individual's approval by the review committee of record (IRB, IACUC, SRS, RDC).

h) Developing and implementing plans for data use, storage, and security that are consistent with VA Directive 6500, Information Security Program, and its implementing handbooks or directives and other legal requirements.

i) Preparing and submitting information, at least annually or as required, on their research program(s) and on each project to the RDC or RDC subcommittee for continuing review as required by the RDC and respective RDC subcommittees.

j) Ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.

k) Conducting Human Subjects Research

   i) The investigator must give first priority to the protection of research subjects, uphold professional and ethical standards and practices, and adhere to all applicable VA and

other federal requirements, including MVAHCS policies and procedures, regarding the conduct of research and the protection of human subjects.

ii) For more information, see VHA Directive 1200.05 and MVAHCS Standard Operating Procedures (SOPs)

l) Conducting Animal Research

i) The use of animals in VA research is a privilege granted with the understanding and expectation that such research is conducted according to the highest ethical and legal standards. The basic principles governing animal research in VA are found in the United States (U.S.) Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

ii) All VA facilities and investigators conducting animal research must comply with the Health Research Extension Act and the Public Health Service Policy, which includes the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, Guide for the Care and Use of Laboratory Animals, and the AVMA Guidelines on Euthanasia.

iii) For more information, see VHA Directive 1200.07 and MVAHCS SOPs.

m) Conducting Laboratory Research / Research with Hazards

i) All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the R&D Committee prior to commencement.

ii) The PI must ensure that all study team members receive required safety training and enforce standards of practice which minimize employee exposures to hazards.

iii) For more information, see VHA Directive 1200.08 and MVAHCS SOPs.

n) Presentation of Research Results

i) VA expects its contributions to medical and scientific research to receive due credit. Research investigators are responsible for complying with the policy to properly cite VA research support.

ii) Investigators must make available to the public all peer-reviewed publications reporting the results of VA Office of Research and Development-funded research without restriction.

iii) Investigators must ensure that any publishing or copyright agreements concerning submitted articles fully comply with VA policy.

iv) Investigators are responsible for depositing manuscripts in PubMed Central operated by the National Library of Medicine (NLM) upon acceptance for publication.

v) For more information, see VHA Directive 1200.19 and MVAHCS SOPs.

o) Invention Reporting and Technology Transfer Compliance

i) Investigators are responsible for ensuring all members of their study teams remain in compliance with VA Technology Transfer requirements for annual training, invention disclosure, and invention certification.

p) Financial Conflict of Interest (COI). Investigators are responsible for completing and filing a COI statement (OGC form 450-ALT) for each VA-approved research project for which s/he serves as investigator or co-investigator. For more information, see MVAHCS RDC SOP 021.

q) Reporting Research Events, Data Security or Privacy Issues, Noncompliance, and Research Misconduct

i) Reportable Events. VA personnel, including WOC and IPA appointees, must ensure:

- Written notification to the applicable subcommittee (IRB, IACUC, and/or SRS) or the RDC within 5 business days after becoming aware of:
  - Any local Serious Adverse Event, Serious Problem, or Reportable Event that is both unanticipated and related to research;
  - Any suspension or termination of VA research by, or at the direction of, any entity external to the facility;
  - Any serious accident, injury, illness, or exposure of a human that may be related to the research;
  - Any apparent unanticipated death, theft, escape, or unexplained disappearance of research animals;
  - Any incident related to research safety that is reportable under relevant VHA Handbooks or applicable Federal requirements, including Occupational Safety and Health Administration (OSHA) requirements.
- Oral notification to the applicable subcommittee (IRB, IACUC, and/or SRS) or RDC immediately upon becoming aware of any human death that may be the related to the research.

ii) Data Security or Privacy Issues. VA personnel must strive to ensure data security and privacy are maintained. In instances when data security or privacy incidents occur, VA personnel must report issues to the Research Compliance Officer, Information Systems Security Officer, applicable subcommittee coordinator, or Research administration for follow-up and determination of whether such issues must be reported through the facility Director to the Office of Research Oversight.

iii) Noncompliance. VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing, within 5 business days after becoming aware of any apparent serious or continuing noncompliance with IRB or other human research protection requirements.

iv) Research Misconduct. VA employees have a responsibility to report suspicions of research misconduct if, after a careful assessment of the facts that are readily available to them in the course of their normal duties, they honestly and reasonably believe there is evidence of research misconduct, defined as fabrication, falsification, or plagiarism.

v) For more information, see VHA Directives 1058 and 1058.02, and MVAHCS SOPs.

4. <u>CHANGE IN PI STATUS:</u>

a) Principal Investigators on VA research projects must maintain a current paid VA appointment. Should this status change (e.g. if the PI becomes a WOC, contract employee, or fee-based provider), the PI is responsible for identifying individual(s) eligible to serve as PI on any affected project(s), and submitting amendment(s) to assign a new PI in a timely manner.

b) MVAHCS Research Office will retain responsibility for monitoring change in VA status of investigators. RDC and/or subcommittee of record will be notified when PI status changes.

c) Upon becoming aware of a change in a PI's VA employment status, the RDC or subcommittee of record for affected protocol(s) will send a courtesy notification to the PI with an expected deadline for the amendment.

d) Should the PI be unable to identify another individual to assume responsibility for an affected study, the PI will instead submit paperwork to close the project.

5. TERMINATION OF MVAHCS AFFILIATION:

Investigators who leave the MVAHCS are responsible for the following:

a) Investigator must ensure that the PI on any affected studies is granted access to all VA data and/or records related to the study. Transfer of data/records to control of the PI must be completed prior to leaving the VA.

b) If investigator is a PI on an active study, procedures under "5. Change in PI Status" above must be followed (a new PI must be identified, or study must be closed).

c) If investigator was previously PI on any closed studies, including studies closed upon leaving VA service, s/he must turn over control of all VA data for those studies to the Research Office for long-term archiving. Transfer of control of data must be completed before investigator leaves VA service.

6. REFERENCES:

MVAHCS Research Service Standard Operating Procedures

VHA Directive 1058 "Office of Research Oversight" (08 November 2024)

VHA Directive 1058.02 "Research Misconduct" (10 July 2020)

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)

VHA Directive 1200.19 "Presentation of Research Results" (10 May 2019)

VHA Directive 1605.01 "Privacy and Release of Information" (24 July 2023)

VHA Handbook 1605.04 "Notice of Privacy Practices" (12 February 2024)

VA Handbook 6500 "Risk Management Framework for VA Information Systems VA Information Security Program" (24 February 2021)

7. **R&D COMMITTEE APPROVAL:** 07 January 2025

8. **RESCISSIONS:** Minneapolis Research Service SOP R&D-004 "MVAHCS Research Investigator Responsibilities" (06 June 2023)

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

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