

SUBJECT: Administrative Expectations for Personnel Conducting Research

1. PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to define the administrative expectations for personnel conducting research at the Minneapolis VA Health Care System (MVAHCS) and outline consequences for failure to adhere to these expectations. This SOP does not address Research Misconduct or Research Impropriety, which are defined and discussed elsewhere (Handbooks 1058.02 and 1058.04; R&D SOP #012). An overview of investigator responsibilities may be found in VHA Handbook 1200.01.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research

AO/R: Administrative Officer for Research

PI: Principal Investigator

RDC: Research and Development Committee

3. OVERVIEW:

The Research & Development Committee (RDC) is responsible for overseeing and maintaining high standards for the research program at the Minneapolis VAHCS. Specifically, it is responsible for “making appropriate recommendations to the Medical Center Director, including... remedial or restrictive action regarding a principal investigator” (VHA Handbook 1200.01). This document describes processes and procedures to deal with repeated administrative delinquency and/or egregious conduct that: (a) unduly burdens the MVAHCS research infrastructure; and/or (b) attracts negative attention from outside entities, including but not limited to research oversight groups.

4. ADMINISTRATIVE EXPECTATIONS:

Investigators are responsible for ensuring that they and their staff promptly complete mandatory paperwork and training as required by the RDC, RDC subcommittees, and Research Administration. Investigators and their staff are also expected to provide timely, informative, and courteous responses to emails and other communications from the Research Office and all other VA entities.

5. ADMINISTRATIVE DELINQUENCY:

The term “administrative delinquency” includes but is not limited to:

- a) *Failure to meet deadlines for required document submissions*, e.g., repeated failure to submit required materials, such as continuing review documents, responses to requests for additional information or modifications to secure committee approval, or Scopes of Practice within required timeframe;
- b) *Failure to maintain required trainings*, e.g., failure to comply with required training on information security, privacy and HIPAA regulations, and other topics as required;
- c) *Failure to respond to official correspondence in a timely and professional manner*, e.g., failure to respond to requests for information.

Administrative delinquency is considered **serious** if it substantively compromises the effectiveness or reputation of the MVAHCS research program and **continuing** if the investigator fails to comply with administrative requirements within the time period specified by the RDC or subcommittee.

6. REPORTING DELINQUENCY:

RDC and RDC subcommittees and Research Office, as applicable, are expected to:

- a) Consistently apply policies for termination or suspension of studies that fail to comply with requirements as described above (see VHA Handbooks 1200.05, 1200.01, 1200.07, 1200.08);
- b) Report delinquency to the investigator's immediate supervisor and the Associate Chief of Staff for Research (ACOS/R); and
- c) Report instances of continuing delinquency/concerns to the RDC for remediation.

7. REMEDATION BY THE RDC:

- a) The RDC will either consider a case of alleged delinquency during a convened meeting of the full committee or will appoint a subcommittee to investigate the case and report back to the full committee.
- b) If the RDC determines that a violation is serious or continuing, it will consider whether to suspend or terminate the project or take or recommend some other action. The investigator will be notified promptly following the meeting at which such determination is made. This notification will include, if applicable, a description of restrictions, required actions, and deadlines for required actions.
- c) Appeals. The investigator may appeal the RDC's decision. An appeal is a request from the investigator to the RDC to reconsider a prior decision.
 - Appeals may only be submitted by the investigator (not by a representative) and must be in writing within 30 days of the meeting at which action was taken.
 - Appeals should be submitted to the Administrative Officer/Research (AO/R) who will convey them to the RDC.
 - The investigator may submit clarifications, dispute facts, and provide additional references, consultants' reports or other material that may support his/her case.
 - The investigator may describe mitigating circumstances.
 - The investigator may request a hearing before the RDC but may not be present during deliberations or voting.
- d) The RDC will be responsible for reporting amendments or reversals of decisions to Officials and Agencies that had previously been notified.
- e) Reinstatement. If the RDC suspends a study, the investigator may ask the RDC to reinstate approval at a later date. If approval is reinstated then the RDC must consider if limitations should be imposed. These may include but are not limited to limiting the number or type of projects an investigator may conduct as principal investigator; mandating supervision of the research by another investigator; or requiring more frequent and/or focused auditing by the Research Compliance Officer(s).

8. REFERENCES:

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

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

VHA Handbook 1200.07 “Use of Animals in Research” (27 May 2005)

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

9. R&D COMMITTEE APPROVAL: 04 June 2019

10. RECISSIONS: Minneapolis Research Service SOP R&D-009 “Administrative Expectations for Personnel Conducting Research” (06 September 2016)

11. EXPIRATION DATE: N/A

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