RESEARCH MISCONDUCT

1. **PURPOSE:** To set policy and procedures for the reporting, investigating, and resolving of complaints alleging research misconduct at the Portland VA Medical Center (PVAMC) consistent with VA Handbook 1058.2.

2. **POLICY:** It is the policy of the PVAMC to sustain public trust in the research enterprise, which requires confidence in the research record and in the processes involved in its ongoing development. To this end allegations of or apparent misconduct in scientific research will be investigated and appropriate action taken against individuals if it is determined that research misconduct has occurred. This policy applies to research and related activities conducted by VA investigators regardless of funding or source of funding. This policy does not deal with other research improprieties that fall outside the definition of research misconduct (see below). Separate VA policies and procedures deal with conflicts of interest, sexual harassment, and violations of federal rules governing protection of human subjects in research and the welfare of laboratory animals.

3. **DEFINITIONS**:

   a. An allegation is a written statement that research misconduct may have occurred, submitted to the potential Respondent's supervisor, Associate Chief of Staff/Research and Development (ACOS/R&D) who acts as the Research Integrity Officer (RIO).
   b. An informant is a person who makes an allegation of research misconduct (whistleblower).
   c. Inquiry is a process in which initial information is gathered solely to determine whether the readily available evidence warrants a formal investigation of research misconduct.
   d. Investigation is a formal process whereby a properly constituted Investigation Committee evaluates all the relevant facts, determines whether the evidence supports a finding of research misconduct, identifies the responsible individual(s), and assesses the seriousness of the misconduct.
   e. Joint Jurisdiction. VA Research may be funded by government entities such as National Institutes of Health, private foundations, or commercial sponsors. VA employees may be affiliated with other entities such as Oregon Health and Science University. These non-VA entities may be allowed to lead inquiries and investigations (if approved by the director), to participate in VA inquiry and investigation committees, or to be informed of the results of inquiries and investigations.
   f. Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
   g. Respondent(s) are the person(s) against whom an allegation of research misconduct is directed or whose actions are the subject of an inquiry or investigation. Use of this term does not imply that the person(s) are, or will be, the subject of a disciplinary proceeding.
   h. Research Integrity Officer (RIO). The RIO is the appointed official who is responsible for receiving and coordinating reviews of formal allegations of research misconduct. At the PVAMC, the ACOS/R&D is designated as the RIO.
   i. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It is not the same as research impropriety, which is defined as any ethical lapse or other impropriety

involving or occurring in connection with research other than research misconduct as defined below.

(1) Fabrication. Fabrication is making up data or results and recording or reporting them.
(2) Falsification. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(3) Plagiarism. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(4) Misrepresentation of one's qualifications or the misrepresentation of one's ability to perform research proposed in applications or similar submissions falls within the definition of research misconduct.

To constitute research misconduct, the behavior must

- represent a significant departure from accepted practices of the relevant research community; and/or
- be committed intentionally, knowingly, or with reckless disregard for the integrity of the research.

To establish a finding of research misconduct, the allegation must be proven by a preponderance of the evidence; i.e., the allegation is more likely than not to be true.

j. Retaliation is taking or threatening to take an adverse action against an informant or other individual in response to a good faith and reasonable allegation or cooperation with an inquiry or investigation of research misconduct. An adverse action may include an intentional failure to take a warranted action.
k. VA employees include paid staff, "without compensation" (WOC) employees, contractors, and Intergovernmental Personnel Agreement (IPA) personnel engaged in or requesting support for VA research. This includes, but is not limited to scientists, trainees, technicians and other staff members, students, fellows, guest researchers, and collaborators who fall within these specified categories.
l. VA facilities: include VA-owned or VA-leased space and space loaned to the VA through a formal agreement with another institution.
m. VA research: research projects that meet any of the following criteria:
    - The study is supported by funds from VA Central Office or funds administered by the Portland VA Research Foundation (PVARF).
    - Study personnel enroll human subjects, obtain informed consent, or carry out research procedures in VA facilities.
    - VA paid employees, VA "without compensation" employees (WOC), or PVARF employees work on the project while on VA or PVARF time.
    - The VA Veterinary Medical Unit is used.
    - The only work performed in VA facilities is performed by an analytical facility (such as a laboratory or radiology) and the individual(s) supervising that work has/have a level of participation in the project that would warrant co-authorship on a publication.

3. RESPONSIBILITIES and EXPECTATIONS:

a. Informants:

(1) VA employees have a responsibility to report suspicions of misconduct in VA research if, after a careful assessment of the readily available facts, they honestly and reasonably believe there is credible evidence of misconduct.

(2) VA employees also have a responsibility to cooperate in good faith with research misconduct investigations whether led by PVAMC or by an agency/entity with joint jurisdiction (see VA Handbook 0700, and 38 CFR Sec. 0.735-12[b]).

(3) VA employees, former VA employees, and applicants for VA employment who make allegations of research misconduct or cooperate with an inquiry or investigation consistent with the Whistleblower Protection Act of 1989, may seek redress for retaliation as provided under that Act (see Title 5 of the United States Code [U.S.C.] Section 1201 Notes, et seq.).

(4) Informants' requests to protect their identities are to be honored as far as possible. In order to complete most investigations, however, an informant's identity and testimony may ultimately be required.

(5) Informants may consult privately with the RIO before making a formal, written allegation.

(6) Informants who make good faith and reasonable allegations of research misconduct must be given an opportunity to provide testimony during the inquiry, to review portions of the Investigation Report pertinent to their own testimony, and to be informed of the general outcome of the inquiry and investigation as it relates to their allegations. Informants do not otherwise have a right to participate in the review or determination of the alleged misconduct case.

(7) VA employees whose research misconduct allegation or cooperation with an inquiry or investigation is not in good faith may be subject to disciplinary measures.

b. Principal Investigators:

(1) Primary responsibility for ensuring the authenticity of reported data rests with the principal investigator. In addition, all investigators identified as authors of a report assume responsibility for the authenticity of the portion of the report to which they contributed.

c. Respondents:(1)Respondents must be given timely, written notification of the allegations made against them, a description of all such allegations, and reasonable access to the data and other evidence supporting the allegations.

(2) Respondents will be given the opportunity to respond to allegations of research misconduct, the supporting evidence, proposed findings of research misconduct, and

proposed corrective actions, if any. They must be promptly notified of final findings and actions.

(3) Respondents must have the opportunity to be interviewed and present evidence during the inquiry and investigation and to provide comments on the investigation report. Respondents are required to cooperate in good faith with any inquiry or investigation conducted.

(4) Respondents may obtain the advice of legal counsel or a personal advisor who is not otherwise involved with the case. The counsel or advisor may be present at interviews with the respondent, but may not speak for, or on behalf of, the respondent during the inquiry or investigation.

(5) Respondents are prohibited from retaliating against informants who make good faith and reasonable allegations of research misconduct, even if such allegations are ultimately not substantiated.

(6) Respondents against whom a finding of research misconduct is made under these procedures must be afforded an opportunity to appeal that finding and proposed corrective action.

(7) If another agency or entity has joint jurisdiction over a misconduct case, additional sanctions within the authority of that agency or entity may also apply.

(8) Respondents who are not found guilty of committing research misconduct must be afforded reasonable assistance in restoring their reputations to the extent that the PVAMC administration deems appropriate, and within the scope of the PVAMC authority.

Comment [v1]: Wording matches VHA Handbook, so I did not change.

d. PVAMC Administration

(1) The PVAMC administration must make diligent efforts within the scope of their authority to protect from retaliation informants who make reasonable good faith allegations of research misconduct or who cooperate with an inquiry or investigation in good faith.

(2) The PVAMC Director is responsible through the ACOS/R&D for appointing committee members, convening inquiries and investigations in a timely manner, defining the scope and authority of the committees, reviewing reports, and communicating with the VISN 20 Director and Office of Research Oversight (ORO).

(3) The ACOS/R&D is appointed by the director as RIO. The RIO

(a) may be consulted by informant(s) prior to submitting a written allegation. The RIO will explain the procedures for making an allegation and their responsibilities and safeguards under these procedures and review the allegation with the informants.

(b) determines whether the alleged activities meet the definition of research misconduct and threshold for formal inquiry.
(c) has the responsibility to inspect and sequester all research records related to a misconduct allegation without notice.
(d) oversees inquiries and investigations, maintaining files of all documents and evidence, ensuring the confidentiality and security of those files, forwarding all information to the appropriate offices or persons as required by these procedures, and otherwise acting as a liaison between the VA facility and ORO.
(e) maintains appropriate safeguards for respondents and informants.

4. PROCEDURES:

a. Allegations

(1) Anyone may make an allegation of research misconduct. VA employees have a responsibility to report suspicious activities. Before submitting a written allegation, potential informants are encouraged to contact the RIO (ACOS/R&D) (email: michael.davey@va.gov or telephone: 503-220-8262 ext. 56627) or the respondent's supervisor. Allegations must be made in "good faith" meaning that the informant has reason to believe the allegation is true and is in a position to know.

(2) The written allegation should include as much relevant detail as possible and be submitted to the RIO. Informants and allegations will be held confidential to the extent possible. Anonymous allegations may be considered, but a full investigation may lead to identification of the informant.

(3) The RIO will determine whether the allegation contains all of the threshold requirements for opening an inquiry.

(4) The RIO will inform the PVAMC Director and COS of all allegations, whether or not they reach the threshold for initiating a formal inquiry.

(5) Within 5 working days, the RIO will inform the informant whether the allegation will lead to a formal inquiry. If not, the informant will have the opportunity to revise and resubmit the allegation.

(6) The RIO, in consultation with PVAMC leadership, will determine whether the alleged misconduct involves other entities such as funding agencies, Portland Veterans Administration Research Foundation (PVARF), or affiliated institutions, such as Oregon Health and Science Institution (OHSU). Entities with joint jurisdiction over the research will be consulted, and may participate in or lead a subsequent inquiry and investigation.

(7) Between the time that a research misconduct allegation is filed and when it is fully resolved, VA may take interim action(s) to minimize harm or threatened harm to research subjects, serious violations of animal welfare requirements, research safety compromises, harm or threatened harm to those involved in the investigation, risks to

public health or safety, loss or destruction of VA funds or property, or possible violations of civil or criminal law associated with the alleged research misconduct. All interim administrative actions taken to minimize damage must be reported to ORO.

b. Inquiry

(1) The PVAMC Director must convene an inquiry within 5 working days after a research misconduct allegation is received if the allegation meets the threshold requirements and the PVAMC has been determined the appropriate entity to lead. The inquiry will be conducted according to rules in VHA Handbook 1058.2. Inquiries may be conducted by either the RIO or an inquiry committee appointed by the PVAMC Director. Any entity with concurrent jurisdiction must designate one representative to participate in the inquiry.

(2) As soon as possible the RIO must sequester all physical materials that might serve as evidence in determining the merits of the research misconduct allegation. In most cases, this should occur before or at the time of notification of the respondent.

(3) The following persons will be provided written notification of the misconduct allegation and the opening of an inquiry:

(a) The named respondent(s) and informant(s)
(b) The VISN20 Director and ORO Central Office
(c) Entities with joint jurisdiction, if any. For PHS-funded studies the Office of Research Integrity will be notified.
(d) The respondent's supervisor

(4) Both the respondent and the informant must be interviewed, if available. Additional individuals who can provide relevant information may also be interviewed. Written transcripts of these interviews must be prepared, provided to the respective interviewees for correction, and included in the record. Outside experts, including VA Regional Counsel, may be consulted, but may not be involved in the decision and must maintain complete confidentiality.

(5) The inquiry must be complete within 30 working days of receipt of the written allegation. A written inquiry report will be prepared by the RIO or Inquiry Committee and sent to the director.

(a) If the report finds insufficient evidence for research misconduct and the director agrees, the case will be terminated.
(b) If the report finds sufficient evidence for research misconduct or the director disagrees with a recommendation to terminate the case, an investigation must be opened.
(c) All individuals and entities notified of the allegation will be notified of the result of the inquiry.

c. Investigation

(1) The PVAMC Director must convene an investigation within 10 working days of the recommendation to open an investigation, and appoint an Investigation Committee. The investigation will be conducted according to the rules in VHA Handbook 1058.2.

(2) The RIO must notify the respondent and informant of the committee's membership. Within 5 working days of receiving such notification, the respondent and the informant may each submit written objections to the selection on the basis of conflict of interest. The final decision to retain or replace committee members belongs to the director.

(3) The Investigation Committee must conduct a thorough review of the research misconduct allegation. They may consider other potential instances of related research misconduct not specified in the allegation; the Inquiry Report; sequestered and submitted materials; interviews with the informant, respondent, and other witnesses; and any other relevant evidence that can be obtained. The committee must reach a decision as to whether and to what extent research misconduct has occurred, the type and extent of misconduct, who is responsible, and what corrective actions are appropriate. VA counsel may be consulted.

(4) The Investigation Committee will produce a draft Investigation Report. The draft Investigation Report will be provided to the respondent, and relevant sections will be provided to the informant. Written comments must be submitted to the committee within 5 working days after receipt. The Investigation Committee makes any necessary revisions to the report and attaches any comments of the respondent and informant to the final Investigation Report.

(5) The final Investigation Report is submitted to the director within 90 calendar days of the start of the investigation.

d. Outcome

(1) The PVAMC Director sends the final Investigation Report with any comments to the director of VISN 20, ORO, and entities with joint jurisdiction. The report is reviewed by the director of VISN20 and by ORO. The final outcome, which may include sanctions, is determined by ORO. ORO notifies the Under Secretary for Health, VISN20 director, PVAMC director, heads of entities with joint jurisdiction, the informant, and the respondent.

(a) If the outcome does not result in a finding of research misconduct, the director will notify other entities and individuals involved and will assist in restoring the respondent's reputation.
(b) If the outcome results in a finding of research misconduct, the respondent has 30 calendar days to appeal the finding to the Under Secretary of Health.

(2) After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all

documents and other materials furnished to the RIO or committees. The RIO will keep the file for at least seven years after completion of the case to permit later assessment of the case. VACO or other authorized personnel will be given access to the records upon request.

e. Timeline

(1) 5 working days after allegation:
- RIO informs informant whether a formal inquiry will result.
- PVAMC Director convenes inquiry if allegation meets threshold requirements and PVAMC has been determined as appropriate entity to lead.
- ORO Central Office and VISN 20 Office are notified of formal inquiry.
- Any joint jurisdictional entity is notified.

(2) 30 working days after allegation:
- Inquiry and final inquiry report must be complete

(3) 10 working days of recommendation to open an investigation:
- Director must convene investigation and appoint investigation committee.
- RIO must notify the respondent and informant of the committee's membership.

(4) 5 working days after notification of investigation committee's membership:
- Respondent and informant may each submit any written objections to the section on the basis of conflict of interest.

(5) 90 calendar days of start of the investigation:
- Final investigation report is submitted to the PVAMC Director. (A draft report will be sent to the respondent and relevant sections to the informant within a reasonable timeframe that allows revisions before the final 90 day deadline. The respondent and informant must be allowed 5 working days from receipt of the draft to submit written comments to the committee.)

(6) 7 days of receiving final report:
- PVAMC Director certifies and transmits to VISN20 Director with copies to respondent, ORO Central Office and head of any joint jurisdiction.

(7) Within 30 days of receiving notice of research misconduct, informant may file a written appeal.

(8) 6 years after investigation complete: RIO will keep all records on file.

5. REFERENCES:

a. Federal Policy on Research Misconduct. 65 Fed. Reg. 76260 (December 6, 2000).
b. VA Handbook 1058.2 dated May 4, 2005. Research Misconduct.
c. VA Handbook 0700, VA Administrative Investigations Handbook.
d. VA Handbook 5021, Employee/Management Relations.
e. Title 5 U.S.C. Section 1201 Notes, et seq. Whistleblower Protection Act of 1989.
f. Title 38 CFR Part 44, Government Wide Debarment and Suspension (Nonprocurement).
g. Title 38 CFR §§ 1.200 through 1.205. Referrals of Information Regarding Criminal Violations.
h. Title 42 CFR Parts 50 and 93. PHS Policies on Research Misconduct.
i. Title 38 CFR Part 0. Standards of Ethical Conduct and other Responsibilities

6. CONCURRENCES: Endorsed by the Research & Development Committee 10/01/2007.

7. RESCISSION: None

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service