

## RESEARCH MISCONDUCT POLICY

1. **PURPOSE:** To establish a policy for the reporting of, investigation into and resolution of research misconduct for all the research conducted at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) or by LSCDVAMC employees or agents on official VA duty time who must comply with all applicable laws in the jurisdiction in which the research takes place.
2. **POLICY:** There is a requirement of high ethical standards for all research activities at the LSCDVAMC. This policy outlines the process by which to inquire, investigate, and resolve promptly and fairly all alleged or apparent misconduct in science regardless of sponsorship.
3. **DEFINITION:**
  - a. **Research Misconduct:**
    - (1) Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct is to be distinguished from honest error and differences of interpretation. It includes, but is not limited to the following.
      - (a) **Fabrication:** making up data or results and recording or reporting them.
      - (b) **Falsification:** 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.
      - (c) **Plagiarism:** the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
    - (2) Misrepresentation of one's qualifications or the misrepresentation of one's ability to perform the proposed research in applications or similar submissions falls within the definition of research misconduct.
    - (3) Abuse of confidentiality, including use of ideas and preliminary data gained from access to privileged information through:
      - (a) editorial review of manuscripts submitted to journals, and/or
      - (b) peer review of proposals being considered for funding by agency panels or by internal committees, such as the Research and Development (R&D)

Committee, Institutional Review Board (IRB), or Institutional Animal Care and Use Committee (IACUC).

(4) To constitute research misconduct, the behavior must:

(a) Represent a significant departure from accepted practices of the relevant research community.

(b) Be committed intentionally, knowingly, or with reckless disregard for the integrity of the research.

(5) 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.

b. An **Allegation** is a written statement that research misconduct may have occurred, submitted to the potential Respondent's supervisor or the Research Integrity Officer.

c. An **Informant** is one who makes an allegation or cooperates with an inquiry or investigation of research misconduct.

d. An **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.

e. An **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.

f. **Research** is the term for all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to: research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

g. **Research Impropriety** is any ethical lapse or other impropriety involving or occurring in connection with research other than research misconduct as defined above. Examples of research impropriety include, but are not limited to, conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human subjects protections and animal welfare requirements.

h. The **Research Integrity Officer (RIO)** is the appointed by the medical center Director and is the official at the LSCDVAMC who is responsible for receiving and coordinating reviews of formal allegations of research misconduct. The Research Compliance Officer (RCO) may serve in this role.

i. The **Research Record** is the record of data or results that embody the facts resulting from scientific inquiry, including, but not limited to, research proposals, physical and electronic laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

j. **Respondent(s)** are the person(s) against whom an allegation of research misconduct is directed or whom 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.

k. **Retaliation** is taking or threatening to take an adverse action within one's authority against an informant 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.

l. **VA Research** is all research (1) funded in whole or in part by the VA; (2) conducted by VA employees within the scope of their VA employment (whether full-time, part-time, or WOC); and/or (3) using VA facilities, equipment, personnel, or patients.

#### 4. **RESPONSIBILITIES:**

a. **Research Personnel:** Researchers are responsible for maintaining the highest ethical standards in their research. Principal investigators are responsible for:

(1) assuring that these standards are communicated to and maintained by all who work under their supervision, directly or indirectly;

(2) assuring the validity of all information communicated by their research groups;

(3) assuring adequate citation of contributions from those within and outside each research group.

#### b. **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 reviews whether led by a VA medical center or 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 and Investigation phases, 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.

**c. Respondents:** The responsibility for ensuring the authenticity of reported data rest 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.

(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 LSCDVAMC management deems appropriate, and within the scope of the LSCDVAMC's authority.

**d. VA Administration:** The LSCDVAMC medical center authorities must make diligent efforts within the scope of their authority to protect from retaliation Informants who make good faith and reasonable allegations of research misconduct or who cooperate with an Inquiry or Investigation in good faith.

(1) The medical center Director is responsible for appointing Committee members, convening Inquiry and Investigations in a timely manner, defining the scope of authority of the Committees, reviewing Reports, and communicating with the VISN 10 Director and Office of Research Oversight (ORO). In the event of a determination of research misconduct, the medical center Director may invoke sanctions according to LSCDVAMC procedures.

(2) The ACOS/R will maintain accurate records and, where required, will ensure that proper and timely reporting to relevant agencies is made for any investigation of research misconduct.

(3) The RIO is appointed by the Director and is responsible for:

(a) Receiving formal allegations of research misconduct, and determining whether the alleged misconduct falls within the scope and meets the required threshold for formal inquiry. The RIO will indicate any deficiencies in the potential allegation, and explain to the Informants the procedures for making an allegation and their responsibilities and safeguards under these procedures.

(b) Inspecting and sequestering all research records related to a misconduct allegation without notice.

(c) Overseeing all 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 LSCDVAMC and Office of Research Oversight.

(d) Coordinating and monitoring the necessary steps for maintaining appropriate safeguards for Respondents and Informants.

## 5. PROCEDURES:

### a. Allegations

(1) Reports of alleged misconduct are to be made directly to the RIO. Allegations must be made in "good faith", meaning that the Informant has reason to believe the allegation to be true and is in a position to know.

(2) The written allegation needs to include all relevant information in detail, including the names of involved individuals and research projects, sources of funding if known, important dates, and any documentation that bears upon the allegation.

(3) 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.

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

(5) The medical center Director, Chief of Staff (COS), and ACOS/R will be informed of all allegations, whether or not they reach the threshold for initiating a formal Inquiry.

(6) Within 5 working days the Informant will be informed whether the allegation will lead to a formal Inquiry. If not, the Informant will have the opportunity to revise the allegation.

(7) The RIO, in consultation with LSCDVAMC leadership, will determine whether the alleged misconduct involves other entities such as funding agencies, VA Medical Research and Education Foundation, or affiliated institutions. Entities with joint jurisdiction over the research will be consulted, and may participate in or lead subsequent Inquiry and Investigation.

(8) Between the time that a research misconduct allegation is filed and when it is fully resolved, LSCDVAMC 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 medical center Director must convene an Inquiry within 5 working days after a research misconduct allegation is received if the allegation meets the threshold requirements and it has been determined that the LSCDVAMC will lead. The Inquiry may be established as an administrative investigation (AI) following medical center policy 000-010.

**(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.

**(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 VISN10 Director and ORO

**(c)** Entities with joint jurisdiction, if any. For Public Health Service (PHS)-funded studies the Office of Research Integrity (ORI) will be notified.

**(d)** The Respondent's supervisor

**(4)** Inquiries may be conducted by either the RIO or an Inquiry Committee appointed by the medical center Director.

**(5)** 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.

**(6)** 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 medical center Director through the COS.

**(a)** If the Report finds insufficient evidence for Research Misconduct, and the medical center Director agrees, the case will be terminated.

**(b)** If the Report finds sufficient evidence for Research Misconduct, or the medical center 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 medical center Director must convene an Investigation within 10 working days of the recommendation to open an Investigation, and appoint an Investigation Committee. The Investigation may be established as an AI following medical center policy 000-010.

(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 medical center Director.

(3) The Investigation Committee is to 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 the Respondent and Informant comments, if any, to the final Investigation Report.

(5) The final Investigation Report is submitted to the medical center Director within 90 calendar days of the start of the Investigation.

**d. Outcome**

(1) The medical center Director sends the final Investigation Report, with comments if any, to the Director of VISN10, ORO, and entities with joint jurisdiction. The report is reviewed by the Director of VISN10 and by ORO. The final outcome, which may include sanctions, is determined by ORO. ORO notifies the Under Secretary for Health, VISN10 Director, LSCDVAMC 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 medical center 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

6. **REFERENCE:** Medical Center Policy 000-010 "Administrative Investigations", Federal Policy on Research Misconduct, Federal Register Vol. 65 No. 235, December 6, 2000 (page 76260-76264)); VHA Handbooks 1058.2 "Research Misconduct, 0700 "Administrative Investigations", and 5021 "Employee/Management Relations; Medical Center Policy 151-016 "Noncompliance in Research", 5 USC 1201 Notes, et seq. Whistleblower Protection Act of 1989; 38 CFR 44 Governmentwide debarment and suspension (nonprocurement); 38 CFR §§ 1.200 through 1.205. Referrals of Information Regarding Criminal Violations.

7. **RESCISSION:** Medical Center Policy 151-017 dated September 1, 2004 has been rescinded. Review date for this policy is September 1, 2010.

8. **FOLLOW UP RESPONSIBILITY:** Associate Chief of Staff for Research

WILLIAM D. MONTAGUE  
Medical Center Director

**APPENDIX:** Flow Diagram

**FLOW DIAGRAM**

