

Version Number: 3	Research & Development Policy 151-07	Supersedes Document Dated: N/A
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I. PURPOSE

The purpose of this policy is to define "misconduct in scientific research," and to establish policies and procedures for the reporting, investigating, and resolving of complaints alleging scientific misconduct by research investigators and scientific staff. The procedures are designed to protect public confidence in the integrity of research conducted in the VA, and at the same time, protect the rights and reputations of individuals accused of misconduct.

In this policy the reference to VA Medical Center shall apply to all research that is conducted completely or partly in the Syracuse VA Medical Center and its affiliated CBOCs, the Canandaigua VAMC and its affiliated CBOCs, and the Bath VAMC and its affiliated CBOCs.

II. POLICY

It is the policy of the Syracuse VA Research and Development (R&D) Service to require high ethical standards for all research activities and, if necessary, to inquire, investigate, and resolve promptly and fairly all alleged, or apparent misconduct in science. In addition, the R&D Service will take appropriate action against individuals if it is determined that misconduct has occurred. This policy is in compliance with and is modeled after VHA Handbook 1058.2.

III. SCOPE

a. The policies and procedures described in this standard operating policy apply to all instances of alleged, or apparent, misconduct involving research, research training, and related activities conducted by VA investigators regardless of source of funding (or even if unfunded). NOTE: *Issues such as conflicts of interest, sexual harassment, etc., that are not primarily scientific, are considered to be outside the scope of this policy.*

b. Investigators receiving support from other Federal agencies such as the National Institutes of Health, or the National Science Foundation, may be subject to additional scientific misconduct policies such as those contained in 42 CFR (Code of Federal Regulations) Subpart A (Public Health Service), or 45 CFR 689.1 through 689.9 (National Science foundation).

IV. DEFINITION

a. Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

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.

b. Research misconduct does not include honest error or differences of opinion.

c. To constitute research misconduct, the behavior must:

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

2. Be committed intentionally, knowingly, or with reckless disregard for the integrity of the research.

d. 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.

V. GENERAL RESPONSIBILITIES

a. The scientific community in general, and VA investigators in particular, are expected to make every effort to prevent scientific misconduct.

b. Primary responsibility for ensuring the authenticity of reported data rests with the principal investigator. In addition, all investigators identified as authors of a report also assume responsibility for its authenticity. An investigator must not knowingly represent as empirical observations data which are newly synthesized, or arbitrarily altered.

c. The appropriate response to a complaint of fraudulent presentation of data is to review the original experimental records. All investigators have the responsibility to maintain a record of all experimental protocols and data sufficient to allow subsequent verification. Written, detailed, and explicit procedures for data gathering, storage, retrieval and analysis must be available in all laboratories. NOTE: *Data must be retained for a minimum of 5 years.*

d. Principal investigators have the responsibility to ensure proper supervision of the research not performed directly by them. Graduate students, trainees, fellows, etc. must be supervised by experienced scientists, and they should be encouraged to present their studies at review sessions or seminars. Publications must give credit to all investigators involved in the research, and all publications must be approved by all co-authors.

e. The Syracuse DVA Medical Center must ensure that sufficient management controls are in effect to preclude the occurrences of all unethical scientific practices in research. Examples of violations of ethical standards include:

- (1) Deliberate fabrication, or falsification, in the conduct, or reporting of research data;
- (2) Plagiarism in scientific publications, or in applications for research support;
- (3) Practices which seriously deviate from those commonly accepted within the scientific community for proposing, reporting or conducting research;
- (4) Misappropriation of research funds;
- (5) Violation of laws established for the protection of human and animal subjects; and
- (6) Retaliation against any individual making allegations of misconduct.

VI. PROCEDURES FOR RESPONDING TO ALLEGATIONS OF SCIENTIFIC MISCONDUCT

The following procedures form the framework when dealing with instances of alleged unethical scientific practice in VA research:

- a. Allegations of unethical practices, which must be in writing, are first reported to the immediate supervisor of the investigator(s) whose actions are in question.
- b. The supervisor is expected to report these allegations promptly to the Research Integrity Officer (RIO), where upon the RIO will notify the VA Medical Center Director.

NOTE: In some instances, the allegations may be resolved through an information fact-finding inquiry among the parties involved. If the allegations are clearly frivolous, self-serving, vindictive, or without supporting documentation, no further action is required; however it would be prudent to retain a record of such inquiries in the event that subsequent allegations are raised which involve issues that were previously reviewed. In no event does this relieve the reporting or alleging parties of submitting the required written reports as noted in VI. a. of this policy.

- c. The RIO must determine whether the allegation contains all of the threshold requirements for opening an inquiry. The requirements include; the allegation involves VA research, the allegation is of research misconduct as defined above, and the allegation on its face contains the elements of a finding of research misconduct. If the allegation meets all of the threshold requirements, an Inquiry can be open.

- d. A fact-finding inquiry is conducted by the RIO and must be thorough (including sequestering of physical materials that might serve as evidence, examinations of data, animals, humans, or budgets in question, interviews of the Respondent and the Informant) and sufficient to withstand higher review if the matter is not withdrawn or terminated. Written notification of the misconduct allegation and the opening of an Inquiry must be given to the named Respondent(s), the Informant, the appropriate VISN Director, ORO Central Office and the research misconduct oversight office for the agency or entity with joint jurisdiction, if any.

e. When the investigator, who is the subject of the allegation, is also a faculty member of the State University of New York Upstate Medical University (SUNY UMU), our affiliated medical school, the Medical Center Director, or COS, will notify the Dean of the SUNY-UMU. In addition, if the investigator has appointments at other institutions (e.g., Syracuse University, University of Rochester), the COS will also notify the Deans and/or other appropriate individuals of such institutions.

f. The RIO must produce an Inquiry Report within 30 days from the initiation of the Inquiry to determine whether there is sufficient evidence to open an Investigation. If the Medical Center Director, COS, and appropriate Dean, determine that substantial evidence suggesting unethical scientific practice is available, they will form a committee to conduct an Investigation. The purpose of an Investigation is to determine whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.

g. If the available evidence suggests a violation of criminal law, the matter must be referred to the Office of the Inspector General.

h. A mutually acceptable determination must be made regarding whether the SUNY-UMU/affiliated university or VA will have the primary responsibility for coordinating the investigation.

i. The committee must consist of members from the staff of Syracuse VA Medical Center and the faculty of the SUNY UMU/affiliated university who possess research expertise. One individual should be appointed to the committee who will be charged with gathering and evaluating evidence. Unless the circumstances indicate otherwise the RIO, or designee, should chair the committee and issue the final report of the findings.

j. Individuals from outside this VA Medical Center, including those from institutions noted above in d., with expertise in the same area of science as the researcher(s) whose practice is in question, may also be added to the committee.

k. If the alleged unethical practice involves the abuse of humans, or animals, the committee is expected to have an active liaison with a representative of the Institutional Review Board, or the Subcommittee on Animal Studies.

l. At the initiation of the investigation, the accused Respondent(s) must be notified immediately, in writing, of the allegations and that a committee of investigation has been formed to consider the allegations. The accused Respondent(s) must be informed of the right to be represented by legal counsel or other personal representative(s). *NOTE: The personal representative(s) may act only in an advisory capacity.*

m. The Medical Center Director and the Dean of the SUNY UMU/affiliated university will determine when other interested parties, such as collaborators, supervisors and agencies sponsoring, or funding, the researcher(s) in question, are to be informed of the pending investigation. In making this determination, consideration should be made to whether preliminary evidence indicates that a serious question concerning the validity of the research exists. *NOTE: Other interested parties might also include other colleges and universities (e.g., Syracuse University) where the accused researcher(s) may have adjunct appointments and/or perform collaborative research.*

n. Once the Investigation begins, the RIO, or designee, must notify the appropriate VA Central Office service (e.g., Medical Research, Health Services R&D, or Rehabilitation R&D) of the investigation, with a critical summary of the facts of the incident. The RIO, or designee, must keep the Medical Center Director informed regarding the progress of the investigation.

o. The committee has discretion in choosing the manner of inquiry which may include one or more of the following:

- (1) The securing and review of documentary evidence including all original experimental records, protocol, and data;
- (2) Interviewing relevant persons, whether in person, or by telephone;
- (3) Group meetings of discussion or inquiry; and/or
- (4) Hearings; If hearings are conducted, sessions of the hearings must be closed so that a fair and judicious investigation, which protects the rights and reputation of all involved, can be maintained. Records of the inquiry will be disclosed only in accordance with law.

p. Files maintained in conjunction with the investigation will not be retrievable by personal identifiers (e.g., name, Social Security number, etc.). If an Agency employee fails to observe this prohibition and maintains investigation records retrieved by personal identifiers, such conduct may constitute a violation of the Privacy Act, i.e., 5 U.S.C. (United States Code) 552a. This violation may lead to a Federal Court imposing civil sanctions against VA and criminal penalties against the responsible employee, and/or appropriate disciplinary action.

q. Both the Respondent and the Informant must be interviewed by the committee of investigation. Both parties will have the opportunity to offer comments and other relevant information and to propose witnesses. The committee will ensure that the information collected is recorded properly and that confidentiality is maintained.

r. The length of time from reporting an instance of possible misconduct to completion of the Investigation should not exceed 90 days, unless circumstances are exceptional. If interval progress reports are made by the investigation committee, they must be provided to the Medical Center Director, ACOS/R&D, Dean of the SUNY UMU/affiliated university, and the director of the appropriate VA Central Office Service.

s. A written summary of the investigation, Investigation Report, must include a summary of the research misconduct allegation, the evidence reviewed, and the Committee's recommendation about whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions.

t. The VA medical center Director may append the Director's own recommendations along with rationale for the recommendations to the Investigation Report. The VA medical center Director must notify the VISN Director of any proposed disciplinary action(s) that the VA medical center Director intends to take.

u. The Investigation Report must be made available to the Respondent(s) for comment and rebuttal. If the text of the summary is acceptable in principle, the signatures of the Respondent(s) should so stipulate. The Investigation Report should also be provided to ORO Central Office and the head of the agency of entity that has joint jurisdiction, if any.

VII. PROCEDURES TO BE TAKEN FOLLOWING COMPLETION OF THE INVESTIGATION AND RECEIPT OF COMMENTS OF INVOLVED RESEARCHERS(S)

a. If the alleged unethical scientific practices are not confirmed by the investigation, the Medical Center Director, ACOS/R&D, Dean of the SUNY UMU, and Deans of other institutions where the individual(s) under investigation have appointments, must take appropriate action to ensure that the reputation of the individual(s) is cleared of suspicion.

b. Other interested parties, such as collaborators, supervisors and agencies sponsoring, or funding, the research, must be notified that the individual(s) suspected to have engaged in alleged unethical practice was absolved of wrong doing by the investigation.

c. The individual(s) must be given the option of having a written notice of clearance sent to the relevant members of the faculty from the Dean of the SUNY UMU/affiliated university, and the VA Medical Center Director.

d. If there is evidence of unethical scientific practice, the VISN Director will review the Investigation Report and make an Adjudication. The purpose of an Adjudication is to make a VA determination, based on the recommendations from the Investigation, as to whether research misconduct occurred, and if so, who is responsible, the type of misconduct involved (fabrication, falsification, and/or plagiarism), the extent or seriousness of the misconduct, and appropriate corrective actions. This review and final decision must be completed by the VISN Director within 30 days of the receipt of the Investigation Report.

e. The VISN Director's final decision is to be transmitted to ORO Central Office along with the Investigation report. If ORO determines that the Inquiry and Investigation and Adjudication substantially adhered to the procedures set forth in this SOP, the VISN Director's decision will be upheld.

f. ORO Central Office provides written notification of the outcome to the Under Secretary of Health; the VISN Director; the VA medical center Director; the head of the agency or entity that has joint jurisdiction, if any; the Informant; and the Respondent.

g. Corrective action proposed in the Investigation Report and Adjudication must be implemented.

h. The Medical Center Director, COS, and Dean of the SUNY UMU/affiliated university, will take action to have all pending abstracts and papers associated with the unethical scientific practices of the researcher(s), withdrawn; they must notify editors of journals in which previous abstracts, articles; and papers relating to the research in question, were published.

i. The Medical Center Director, Dean of the SUNY UMU/affiliated university, and VA Under Secretary for Health, in consultation with legal counsel, should decide if the release of information, regarding the scientific misconduct, to the media is warranted.

j. The named Respondent may file an appeal to the VA Under Secretary of Health and a copy sent to ORO Central Office within 30 days of receiving the notice of research misconduct finding. The appeal must include the notice of research misconduct finding, the final Investigation Report, the precise findings or proposed corrective actions that are being appealed, a statement of the ground for the appeal, and any addition evidence that supports the ground for appeal. The Under Secretary of Health makes a final decision.

VIII. REFERENCES

VHA Handbook 1058.2, Research Misconduct, Dated May 4, 2005.

IX. RESCISSIONS

R&D SOP 151-05 "Misconduct in Scientific Research" dated May 2007.



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