

RESEARCH MISCONDUCT POLICY

1. PURPOSE

To set policy and procedures for the reporting, investigating, and resolving of complaints alleging research misconduct at the Nebraska Western Iowa Healthcare System (NWIHCS) consistent with VA Handbook 1058.2.

2. POLICY

It is the policy of the NWIHCS 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 source of funding (or even if unfunded). This policy does not deal with other research improprieties that fall outside the definition of research misconduct (see below). Separate VA policies and procedures exist which deal with conflicts of interest, sexual harassment, and violations of federal rules that govern protection of human subjects in research and the welfare of laboratory animals.

3. BACKGROUND

A. The procedures in this policy are:

(1) Intended to protect the public's confidence in the integrity of VA research by minimizing the incidence of research misconduct and by providing a fair and timely manner of responding to research misconduct allegations.

(2) Designed to maintain appropriate safeguards for those accused of research misconduct (Respondents) and those who make allegations of research misconduct or otherwise cooperate with Inquiries and Investigations (Informants).

B. As a public agency, NWIHCS has an ethical obligation to preserve public trust in the integrity and quality of research carried out by its investigators, among its patients, and in its facilities. To protect that trust, NWIHCS has a responsibility to:

(1) Ensure that its research is above reproach;

(2) Implement mechanisms that enable concerns regarding possible research misconduct to be brought to the attention of appropriate institutional officials so that they may address these promptly and thoroughly; and

(3) Ensure that such mechanisms are objective and fair, respecting the rights and well-being of all individuals who may be involved when allegations of misconduct are raised.

C. This Policy has been created for the administrative efficiency of VA and does not establish rights for any individual. However, individual rights or obligations that must be observed in the course of investigations may arise under other policies, regulations, laws, or governing collective bargaining agreements.

D. Research Misconduct is prohibited. VA is committed to conducting all of its research activities with utmost integrity, adhering to scientifically sound practices as well as ethical principles. To that end, VA employees and any other individuals engaged in VA research are prohibited from committing research misconduct. VA maintains the right to:

- (1) Investigate all allegations of such research misconduct,
- (2) Use all legally permitted means for conducting investigations, and
- (3) Impose appropriate corrective actions in order to protect its research funds and the public trust.

E. Federal Policy on Research Misconduct:

(1) This Policy conforms to the requirements of the Federal Policy on Research Misconduct at 65 Federal Register (Fed. Reg.) 76260 (December 6, 2000). The Federal policy sets forth the responsibilities of Federal agencies (which “have ultimate oversight authority for Federally funded research”) and research institutions (which “bear primary responsibility for prevention and detection of research misconduct and for the Inquiry, Investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution” [see Fed. Reg. 76263]).

(2) For purposes of this Policy, the “research institutions” are the VA medical centers at which VA research is conducted. The “Federal agency” is VA which encompasses and oversees the VA medical centers.

4. DEFINITION OF RESEARCH MISCONDUCT

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.

5. SCOPE

A. These procedures apply to all VA employees, including “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.

B. Ethical lapses or other improprieties that do not fall within the definition of research misconduct in paragraph 4 are not covered by this Policy. Examples of such improprieties include: conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human subjects protections and animal welfare requirements. These improprieties are subject to other VA regulations, policies, and procedures, and in some cases, other laws and regulations. If a matter involves both research misconduct and non-research misconduct issues, a single administrative investigation may be convened to review all of the related issues in order to promote administrative efficiency (see VA Handbook 0700). **NOTE:** *If a consolidated administrative investigation is convened, the investigation procedures must be consistent with the specifications of Handbook 1058.02 and must contain a distinct recommendation regarding the research misconduct issue(s).*

C. Misrepresentation of one’s qualifications or the misrepresentation of one’s ability to perform the proposed research in merit review applications or similar submissions falls within the definition of research misconduct.

D. Authorship disputes other than plagiarism are not covered by this Policy.

E. Although this Policy does not specifically cover patient safety issues, it does require that interim actions be taken when harm or threatened harm to research subjects is discovered during the course of a research misconduct proceeding. **NOTE:** *VHA policy regarding patient safety is set forth at VHA Handbook 1050.1.*

6. DEFINITIONS

A. Allegation - An allegation is a written statement that research misconduct may have occurred, submitted to the potential Respondent’s supervisor or the Research Integrity Officer.

B. Debarment- Debarment is an action taken by the VA debarring official to exclude a Respondent from participating in the covered transactions listed at Title 38 Code of Federal Regulations (CFR) 44, Subpart B. **NOTE:** *For purposes of this Policy, the*

debaring official is VA's Under Secretary for Health. A debarment by VA has government-wide effect, unless a specific exception is granted.

C. Fabrication- Fabrication is making up data or results and recording or reporting them.

D. 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.

E. Good Faith and Reasonable Allegation or Cooperation- A good faith and reasonable allegation of research misconduct is an allegation which the Informant believes and which a person in the Informant's position could reasonably make, in light of the readily available evidence. An allegation is not made in good faith if made with reckless disregard for or willful ignorance of facts that would negate the allegation. Good faith cooperation with a research misconduct Inquiry or Investigation means cooperating honestly and forthrightly with those conducting the Inquiry or Investigation.

F. Informant - An informant is one who makes an allegation or cooperates with an Inquiry or Investigation of research misconduct.

G. Inquiry- 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.

H. Investigation- 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.

I. Plagiarism- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

J. Research- 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.

K. Research Impropriety- Research impropriety is any ethical lapse or other impropriety involving or occurring in connection with research other than research misconduct as defined in paragraph 4. Examples of research impropriety include, but are not limited to, conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human subject's protections and animal welfare requirements.

L. Research Integrity Officer (RIO) - The RIO is the appointed official who is responsible for receiving and coordinating reviews of formal allegations of research misconduct.

M. Research Misconduct (or Misconduct) - See paragraph 4.

N. Research Record- 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.

O. Respondent(s) - 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.

P. Retaliation- 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.

Q. Suspension- Suspension is an action taken by the VA suspending official that immediately prohibits a Respondent from participating in covered transactions listed at 38 CFR 44, Subpart B for a temporary period, pending completion of an investigation and ensuing proceedings. **NOTE:** For purposes of this Policy, the suspending official is the Under Secretary for Health.

R. VA Research- VA research is all research:

- (1) Funded in whole or in part by 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.

7. RESEARCH INTEGRITY OFFICERS (RIOs)

A. The medical center Director designates a permanent RIO position responsible for overseeing misconduct allegations at that facility. The Director delegates responsibility to the RIO for overseeing all aspects of research misconduct Inquiries and Investigations except as otherwise provided herein. The position of RIO must be administratively assigned to either the Associate Chief of Staff (ACOS) for Research, the Research Coordinator, the Research and Development Committee Chairperson, or another similar individual within the research program who has sufficient institutional authority and experience to be able to fulfill the required duties.

B. The RIO is responsible for:

- (1) Receiving formal allegations of research misconduct, determining whether the alleged misconduct falls within the scope and meets the required threshold of these procedures, 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 VA facility and ORO.
- (2) Coordinating and monitoring the necessary steps for maintaining appropriate safeguards for Respondents and Informants.

(3) Receiving initial and continuing education and training in the handling of research misconduct allegations according to the information in this Policy, and transmitting the information obtained in such training to members of Inquiry and Investigation Committees.

(4) Keeping the scientific and administrative staff of the VA medical center informed of the policies and procedures in this Policy and for overseeing the VA medical center's compliance with the Handbook's provisions.

(5) Demonstrating objectivity, both apparent and actual, in carrying out RIO duties.

C. Conflict of Interest- If the RIO has a conflict of interest, or apparent conflict of interest, in a particular case because of a significant relationship with the Respondent, the Informant, or the underlying research project or its investigator(s), the RIO must not participate in the oversight of that particular misconduct case. The VA medical center Director must appoint an acting RIO to oversee such cases.

8. INFORMANTS

A. 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.

B. 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]).

C. VA 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.

D. 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.).

E. 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.

F Informants may consult privately with the RIO before making a formal, written allegation. The RIO must:

(1) Indicate any deficiencies in the potential allegation, and

(2) Explain to the Informants the procedures for making an allegation and their responsibilities and safeguards under these procedures.

G. 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. **NOTE:** *Informants do not otherwise have a right to participate in the review or determination of the alleged misconduct case.*

H. VA employees whose research misconduct allegation or cooperation with an Inquiry or Investigation is not in good faith may be subject to disciplinary measures.

NOTE: *A “Summary of Obligations and Rights Related to Investigation Witnesses,” located in VA Handbook 0700, is applicable in research misconduct proceedings except as otherwise provided in this Policy.*

9. RESPONDENTS

A. 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.

B. 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.

C. 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 pursuant to this Policy. Inquiries and Investigations proceed regardless of Respondents' cooperation, and misconduct determinations are based on the available evidence.

D. 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.

E. 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. To the extent that allegations of research misconduct constitute disclosures under the Whistleblower Protection Act of 1989, individuals making such disclosures are covered by the protections of that Act, including protection from retaliation.

F. Respondents against whom a finding of research misconduct is made under these procedures must be afforded an opportunity to appeal the finding and proposed corrective actions according to VA Handbook 1058.02.

G. 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.

H. Respondents who are not found guilty of committing research misconduct must be

afforded reasonable assistance in restoring their reputations to the extent that the VA medical center management deems appropriate, and within the scope of the VA medical center's authority. For example, the VA medical center might publicize the outcome in forums in which the allegation was previously publicized (if any) and/or expunge references to the misconduct allegation from the Respondent's personnel file.

10. PRIVACY AND CONFIDENTIALITY

The privacy of all participants and the confidentiality of information gathered in a research misconduct proceeding are to be preserved by all persons to the extent possible consistent with a fair and thorough investigation and as allowed by law (see VA Handbook 0700).

- A. Only those individuals who are specifically authorized to review a misconduct allegation will be provided with nonpublic information in connection with the misconduct proceeding. Any person who receives such information as part of a misconduct proceeding is obligated to keep that information confidential until otherwise made public or as required by law.
- B. Records maintained by the VA, its local facilities and their affiliates, in connection with and during the course of a research misconduct proceeding will be protected to the extent permitted by law from public disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a).
- C. Individual case files are not to be listed or retrievable by individual name or any other information that could easily identify the Respondent or Informant. Case files must be stored in a secure location. Copies of file documents may be made on a limited basis for the purpose of review by authorized individuals.

11. RECORD RETENTION AND ACCESS

All documents and evidence obtained or generated for a research misconduct investigation must be carefully secured and itemized. The requirements for obtaining, maintaining, and making accessible these documents and/or evidence (the record) are:

- A. The RIO, the Inquiry and Investigation Committees, and ORO have the right to inspect and sequester all research records related to a misconduct allegation without notice.
- B. Reasonable, supervised access to, or copies of, the original data may be provided to Respondents so that they can continue their research prior to completion of misconduct proceeding.
- C. After a research misconduct case is closed, the RIO's office must securely retain all research misconduct allegations and Inquiry and Investigation Reports with the underlying evidence, or copies, as appropriate, regardless of merit or outcome, until expiration of their authorized retention period. A research misconduct case is considered closed for purposes of this paragraph if and when:

- (1) ORO dismisses the case;
- (2) The case is terminated after an Inquiry;

(3) The VISN Director does not find research misconduct, and ORO reviews and provides notification of that outcome;

(4) The VISN Director finds research misconduct, and the Respondent does not file a written appeal within 30 days of receiving the notice of research misconduct finding; or

(5) The Respondent appeals a finding of research misconduct, and the Under Secretary for Health makes a final decision (including any reconsideration of a debarment decision) in writing.

D. Upon request, ORO must be given immediate access to any and all materials retained by a VA medical center in connection with a research misconduct proceeding.

12. GENERAL PROCEDURES

A. VA Handbook 0700, Administrative Investigations. Inquiries and Investigations of research misconduct under this Handbook constitute specialized Administrative Investigations (AIs) as described by VA Directive and accompanying Handbook 0700.

(1) The requirements set forth in VA Handbook 0700 must be observed in all research misconduct Inquiries and Investigations except to the extent that any provision of Handbook 1058.02 contradicts a provision of VA Handbook 0700. In all research misconduct Inquiries and Investigations, the provisions of this Handbook take precedence over any contrary provision of VA Handbook 0700.

(2) Consistent with this Policy, the following points must be observed:

(a) For purposes of research misconduct Inquiries and Investigations, the "Convening Authority" (see VA Handbook 0700) is the VA medical center Director, or Chief Executive of the VA facility. Once an Inquiry or Investigation has been convened, the RIO is delegated the administrative authority over the Inquiry and Investigation.

(b) Evidence must be collected according to the provisions in VA Handbook 0700.

B. Administrative Discretion. Particular circumstances in individual cases of alleged research misconduct may dictate variation from the procedures in this Policy when deemed in the best interests of VA. Any significant change from normal procedures must be pre-approved by ORO Central Office and must ensure fair treatment of the Respondent. The Respondent should be notified of any such significant changes.

C. Joint Jurisdiction. Other non-VA agencies or entities (e.g., academic affiliates of the NWHCS) may have concurrent jurisdiction over the same research project, or parts thereof that is the subject of a VA research misconduct Inquiry and Investigation. In such cases, NWHCS must coordinate its response to allegations of research misconduct with the relevant non-VA agencies and/or entities, in order to maximize procedural uniformity and minimize duplication while recognizing institutional autonomy. NWHCS, in a good faith effort to effectuate a coordinated response, must adhere to the following guidelines:

1) For every research misconduct allegation received, the RIO must determine whether and what other non-VA agencies or entities have joint jurisdiction over the underlying research. Joint jurisdiction may be exerted by agencies or entities that co-sponsor or otherwise support the research, employ or provide academic privileges to the principal investigator(s) or support staff, or provide regulatory oversight. Examples include, but are not limited to: the VA medical center's academic affiliate, the Public Health Service (PHS) of the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and other sponsors and regulators.

(2) The RIO must notify all non-VA agencies or entities that have joint jurisdiction over a research project of any misconduct allegation regarding such research. This notice needs to be directed to the office(s) that provide oversight of research misconduct; e.g., the Office of Research Integrity (ORI) for the PHS.

(3) Wherever possible, the VA medical center and the non-VA agencies or entities with concurrent jurisdiction are encouraged to perform a joint Inquiry, and if warranted, a joint Investigation. Each agency or entity with jurisdiction must designate at least one representative to participate in the Inquiry and Investigation. The qualifications of such representative are to be determined by each agency's or entity's own policies and procedures.

(4) Through informal negotiation between NWHCS and the non-VA agencies or entities with concurrent jurisdiction, a mutual determination must be made as to which agency or entity will take the lead in conducting the joint Inquiry and Investigation. Factors to consider in making this determination include, but are not limited to, which agency or entity:

- (a) Is the primary sponsor or funder of the underlying research;
- (b) Approved the underlying research;
- (c) Is the primary employer of the Respondent;
- (d) Operates the facilities that were used to conduct the underlying research; and
- (e) Has the resources and personnel best suited to conducting a timely and thorough Inquiry and Investigation.

(5) The applicable procedures for conducting an Inquiry and Investigation are those of the agency or entity that takes the lead. NWHCS and other non-VA agencies or entities will make, to the extent possible, their respective research misconduct procedures compatible in carrying out the joint Inquiry and Investigation.

(6) If a non-VA agency or entity is given primary responsibility for conducting the joint Inquiry and Investigation, at least one VA employee with research experience and at least 5/8 status must be included as a full participant in the Inquiry and Investigation.

(7) Each Inquiry and Investigation must result in a single set of recommendations, although a minority opinion may be produced if the lead agency's or entity's procedures so specify.

(8) Each agency or entity with concurrent jurisdiction must follow its own procedures for adjudicating and appealing research misconduct cases. No agency or entity is bound by another's adjudication or appeal decision. Each agency or entity may implement administrative actions in accordance with its own laws, regulations, policies, or contractual procedures, although non-procurement debarments and suspensions are applied across the Federal government pursuant to Executive Order 12549.

(9) Each agency or entity is to give timely notice to the other agencies or entities with concurrent jurisdiction of the final outcome of its adjudication and appeal, if applicable.

D. Interim Actions- Between the time that a research misconduct allegation is filed and when it is fully resolved, VA may take interim action(s) as necessary.

(1) The VA medical center must immediately notify ORO Central Office of the following, if present: 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 Central Office.

(2) When Government-wide suspension is determined to be appropriate, the procedures set forth at 38 CFR 44, Subpart G, must be followed.

(3) If evidence of criminal activity is discovered in connection with a research misconduct proceeding, the provisions at 38 CFR §§ 1.200 – 1.205 for reporting criminal matters must be followed. If there is reasonable indication of a possible criminal violation, the VA medical center must promptly refer the matter to the VA Inspector General, or other appropriate investigative body.

(4) Nothing in this Policy is to be construed as limiting the VA medical center's duty to cooperate with any concurrent VA or non-VA administrative or investigative proceeding authorized by law, including the sharing of information and investigative materials to the extent permitted by law and VA policy.

E. Admissions. Prior to the completion of a case, the Respondent might admit to having committed misconduct. Such admission by itself is not grounds for termination of the case. Any admissions must be placed in writing and signed by the Respondent and a witness. Additional investigation may be necessary to discover the full extent of the Respondent's misconduct or the roles of other potential Respondents. All of the elements of a finding of research misconduct, if not evident in the admission, must be established by a full Investigation.

F. Respondent's Employment Status. Termination of a Respondent's VA employment, by resignation or otherwise, does not preclude the initiation or continuation of an investigation of misconduct alleged to have occurred during the Respondent's VA employment. If a former VA employee chooses not to cooperate with an investigation, all other available testimony and evidence is reviewed.

G. Federal Tort Claims Act (FTCA). As VA employees acting within the scope of their employment, the RIO, members of the Inquiry and Investigation Committees, and other VA support staff are protected from personal liability in accordance with the FTCA. Agencies or entities with joint jurisdiction in particular cases are responsible for providing liability coverage for their employees who participate in a research misconduct proceeding. Non-VA consultants who are asked to provide advice in an investigation need to be formally designated as WOC employees, unless they are contractors.

13. ALLEGATIONS

A. Referrals. All formal allegations of research misconduct must be referred to the RIO. If ORO or any other VA office receives a misconduct allegation concerning VA research at NWHCS, that office must forward the allegation, with the Informant's knowledge and permission, to the RIO.

B. Good Faith and Reasonable. Allegations of research misconduct must be made in good faith and must be reasonable. A misconduct allegation not made in good faith may result in the waiver of any and all protection privileges. A "good faith and reasonable allegation" consists of the following:

(1) The Informant must believe in the substance of the allegation, and the allegation must be one which a person in the Informant's situation could reasonably make.

(2) The Informant needs to have made a reasonable inquiry into the matter before formally alleging research misconduct. Such inquiry might include raising the concerns with the suspected individual(s) or the individual(s)' colleagues and supervisor. The Informant, however, need not place the Informant's own interests in jeopardy in inquiring about the matter.

(3) An allegation is not made in good faith nor reasonable if made with reckless disregard for or willful ignorance of facts that would negate the allegation.

C. Formal Allegation:

(1) If possible, allegations of research misconduct must be made in writing.

(2) The written allegation normally is given to the potential Respondent's supervisor who must then forward the allegation immediately to the RIO. If the Informant prefers, however, the Informant may submit the allegation directly to the RIO. The 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) The RIO must promptly notify the VA medical center Director of all research

misconduct allegations received.

D. Anonymity- Anonymous allegations of research misconduct may be evaluated under these procedures. However, a complete investigation and adjudication of a misconduct allegation often requires the participation of an identified Informant. An anonymous allegation that does not meet the required threshold will not be pursued.

E. Required Threshold- Upon receipt of a research misconduct allegation, the RIO must determine whether the allegation contains all of the threshold requirements for opening an Inquiry. Before an Inquiry is opened, the RIO must determine that the allegation meets all of the following requirements:

(1) The allegation involves VA research as defined in subparagraph 6R

(2) The allegation is of research misconduct as defined in paragraph 4.

(3) The allegation on its face contains the elements of a finding of research misconduct as defined in paragraph 4. The misconduct as alleged must represent a significant departure from accepted practices of the relevant research community and must be committed intentionally, knowingly, or with reckless disregard for the integrity of the research. An allegation that is clearly frivolous and without any basis in fact or reason fails to meet the required threshold for opening an Inquiry.

F. Deficient Allegations- If the allegation fails to meet one or more of the threshold requirements in the preceding subparagraph, the VA medical center Director must notify the Informant, in writing, that a research misconduct case will not be opened.

(1) The notification must set forth the particular threshold requirement(s) that the allegation fails to meet.

(2) A copy of this notification is to be forwarded to the appropriate VISN Director and retained in a secure file for a minimum of 3 years.

(3) If appropriate, the RIO may process the allegation under appropriate other procedures or direct the Informant to another office that may have jurisdiction over the allegation.

(4) If the Informant amends and resubmits the allegation, the RIO must reassess whether the amended allegation meets the threshold requirements.

G. Other Information Sources. Information about potential research misconduct from sources other than an Informant (e.g., media, other agencies) may also lead to the opening of an Inquiry if the threshold requirements are met. The procedures in this Policy apply in such cases.

14. INQUIRY

A. Applicability- The procedures outlined in this paragraph apply whenever NWHCS takes the lead in conducting an Inquiry. If a non-VA agency or entity with joint jurisdiction takes the lead in conducting the Inquiry, that agency or entities misconduct Inquiry procedures apply.

B. Purpose- If a research misconduct allegation meets the threshold requirements of these procedures; an Inquiry must be initiated for the sole purpose of determining whether sufficient evidence exists to open a formal Investigation.

C. Initiation of Inquiry

(1) The VA 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 NWHCS will take lead responsibility for the Inquiry.

(2) The following persons must be provided written notification of the misconduct allegation and the opening of an Inquiry:

(a) The named Respondent(s);

(b) The Informant;

(c) The appropriate VISN Director;

(d) ORO Central Office; and

(e) The research misconduct oversight office for the agency or entity with joint jurisdiction, if any.

(3) The notification must include the name of the Respondent(s), the nature of and basis for the allegation, and the research funding involved.

D. Sequestration of Physical Evidence- 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 (see VA Handbook 0700). In most cases, sequestration must take place prior to, or at the time of, notification to the Respondent.

E. Inquiry Review- An Inquiry consists of a review of the research misconduct allegation, sequestered and submitted materials, and any other readily available evidence, followed by a decision as to whether sufficient evidence exists to open an Investigation. The review must adhere to the following requirements:

(1) The Inquiry Review (including final Inquiry Report) must normally be completed within 30 days from the initiation of the Inquiry. If an extension is required, the VA medical center Director shall submit a timely request to ORO Central Office which may grant such request at its discretion.

(2) Inquiries may be conducted by either the RIO or an Inquiry Committee appointed by the VA medical center Director. The procedures in VA Handbook 1058.02 are to be carefully reviewed at the first Inquiry Committee meeting and the scope of the Committee's Inquiry needs to be clearly understood.

(3) Any agency(s) or entity(s) with concurrent jurisdiction over a research misconduct allegation must designate one representative to participate in the

Inquiry, either in conjunction with the RIO or as a member of an Inquiry Committee.

(4) If the RIO or any member of the Inquiry Committee has an actual or apparent conflict of interest that cannot be resolved with respect to a particular case, such individual must be replaced by another eligible individual. A conflict of interest may include, but is not limited to, a close familial, personal, or professional relationship with the Respondent or Informant, the nature of which creates a strong potential for biasing the individual's decision-making.

(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 (see VA Handbook 0700).

(6) Subject-matter experts from within or outside VA may be consulted to aid in the analysis of the evidence. Regional Counsel may also be consulted on legal matters. Persons other than the RIO, or Inquiry Committee members, may not participate in the substantive decision-making and must maintain strict confidentiality.

(7) After the evidence is reviewed, a decision must be made whether an Investigation is to be opened. Evidence that would raise a significant suspicion of research misconduct to a reasonable person is sufficient to justify opening a formal Investigation.

F. Inquiry Report- For every case in which an Inquiry is initiated, the RIO, or Inquiry Committee if applicable, must produce an Inquiry Report that summarizes the research misconduct allegation, the evidence reviewed, and how the evidence supports the recommendation to open or not open an Investigation. The Inquiry Report may be presented in summary format (see VA Handbook 0700).

G. Termination of VA Case

(1) If the RIO, or Inquiry Committee, finds that the available evidence is insufficient to justify opening an Investigation, and the VA medical center Director concurs, the VA case will be terminated; however, the case file must be retained until expiration of the authorized retention period.

(2) Written notice of the VA case closure must be provided to the Respondent; the Informant; the VISN Director; ORO Central Office; and the research misconduct oversight office for the agency or entity with joint jurisdiction, if any. The RIO must forward the Inquiry Report to the appropriate VISN Director, ORO Central Office, and the research misconduct oversight office for the agency or entity with joint jurisdiction, if any.

(3) The Informant may file a subsequent allegation of research misconduct, but an Inquiry should not be reopened unless substantially new allegations are made or new evidence is provided.

H. Decision to Open an Investigation- If the RIO, or Inquiry Committee, finds that the

available evidence is sufficient to justify opening an Investigation, or if the VA medical center Director disagrees with a recommendation to terminate the case, an Investigation must be opened.

15. INVESTIGATION

A. Applicability- The procedures outlined in this paragraph apply whenever NWHCS takes the lead in conducting an Investigation. If a non-VA agency or entity with joint jurisdiction takes the lead in conducting the Investigation, that agency's or entity's misconduct Investigation procedures will apply.

B. Purpose- If the Inquiry results in a recommendation to open an Investigation, an Investigation must be initiated for the purpose of determining whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.

C. Initiation of Investigation- The VA medical center Director must convene an Investigation, including the selection of an Investigation Committee, within 10 working days of a recommendation to open an Investigation. A Charge Letter must be issued according to VA Handbook 0700. Written notification of the Investigation must be made to the persons listed in subparagraph 14C (2). Such notice must include the name of the Respondent(s), the nature of and basis for the allegation, any additional areas of potential investigation, and the research funding involved.

D. Sequestration of Physical Evidence- As soon as possible and to the extent not done so during the Inquiry, the RIO must sequester all physical materials that might serve as evidence in determining the merits of the research misconduct allegation (see VA Handbook 0700).

E. Composition of the Investigation Committee- Each Investigation must be conducted by an Investigation Committee composed of three to five individuals. The membership requirements of this Investigation Committee are as follows:

(1) The Investigation Committee must be constituted within 10 working days of the Inquiry's recommendation to open an Investigation.

(2) The Investigation Committee may be either a standing committee which conducts all research misconduct Investigations for the VA medical center or an ad hoc committee reconstituted for each new misconduct allegation.

(3) Members of the Inquiry Committee, if any, may serve on the Investigation Committee.

(4) Investigation Committee members need to be employees of the VA medical center, preferably with relevant research experience. The VA medical center Director is responsible for selecting these Committee members.

(5) Each Investigation Committee must be directed by a Chair who is a VA medical center employee with 5/8 or greater appointment and is actively involved with VA research either as an investigator or as an administrator.

(6) Any agency or entity with concurrent jurisdiction over the matter must designate one representative to be a member of the Investigation Committee. The qualifications of that individual are to be determined by the agency's or entity's own policies and procedures. If the other agency or entity does not or cannot designate an individual, the Investigation Committee may be composed entirely of employees of the VA medical center.

(7) An Investigation Committee member who has an actual or apparent conflict of interest that cannot be resolved with respect to a particular case must be replaced by another eligible individual. A conflict of interest may include, but is not limited to, a close familial, personal, or professional relationship with the Respondent or Informant the nature of which creates a strong potential for biasing the Committee member's decision-making.

(8) The RIO must notify the Respondent and Informant of the Committee's membership upon selection. Within 5 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. Any objections must be documented in the case record. The final decision to retain or replace Committee members belong to the VA medical center Director.

F. Investigation Review- The Investigation Committee is to conduct a thorough review of the research misconduct allegation; any other potential instances of related, research misconduct not specified in the allegation; the Inquiry Report; sequestered and submitted materials; 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, who is responsible, and what corrective actions are appropriate. This review must adhere to the following guidelines:

(1) The Investigation Review (including final Investigation Report) normally must be completed within 90 days from the initiation of the Investigation. If an extension is required, the VA medical center Director must notify ORO Central Office at least 5 working days prior to the end of the initial review period. ORO may grant an extension at its discretion.

(2) The procedures in this Policy, VA Handbook 1058.02 and VA Handbook 0700 are to be carefully reviewed at the first Investigation Committee meeting, and the scope of the Committee's investigation must be clearly understood.

(3) If additional Respondents or substantively new allegations are added in the course of the Investigation, notification of these additions must be given in accordance with subparagraph 15C.

(4) The Investigation Committee must interview both the Respondent and the Informant if available. If possible, additional individuals who can provide relevant information must be interviewed. Written transcripts of the interviews are to be prepared, provided to the respective interviewees for correction, and included in the record (see VA Handbook 0700).

(5) Subject-matter experts from within or outside VA may be consulted to aid in the analysis of the evidence. Regional Counsel may also be consulted on legal

matters. Persons who are not members of the Investigation Committee may not participate in the Committee's substantive decision-making and must maintain strict confidentiality.

NOTE: *The Investigation Committee is encouraged, as a general matter, to adhere to the "Tips for Effective Investigations" located in VA Handbook 0700.*

(6) After reviewing the evidence, the Investigation Committee must decide by consensus whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions. If a consensus cannot be reached on one or more of these questions, the Investigation Report must note the area(s) of disagreement, the arguments supporting and opposing the various viewpoints, and the majority opinion, if any.

G. Investigation Report

(1) The Investigation Committee is to produce an Investigation Report that summarizes 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 (see VA Handbook 0700).

(2) The Investigation Report must be provided to the Respondent, and the portions of the Investigation Report related to the initial Informant's role and testimony must be provided to the Informant, for their responses. Written comments must be submitted to the Committee within 7 days. The Investigation Committee makes any necessary revisions to the report and attaches the Respondent and Informant comments, if any, to the final Investigation Report.

H. Certification and Transmittal- Within 7 days of receiving the final report from the Investigation Committee, the VA medical center Director must certify completion of the Investigation according to VA Handbook 0700, and transmit the final Investigation Report with all supporting documents to the VISN Director to which the VA medical center reports.

(1) Along with the Investigation Report, the VA medical center Director may append the Director's own recommendations. The Director's recommendations may concur with, or differ from, the recommendations of the Investigation Committee. The rationale for any recommendation that differs from that of the Investigation Committee must be provided.

(2) 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.

(3) Copies of the final Investigation Report and the VA medical center Director's recommendations are to be provided to the Respondent, ORO Central Office, and the head of the agency or entity that has joint jurisdiction, if any.

16. APPEALS

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 as specified in VA Handbook 1058.02

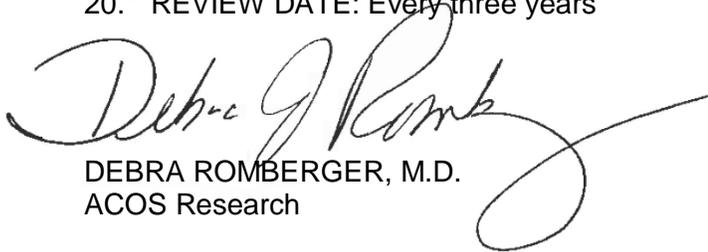
17. REFERENCES

- A. Federal Policy on Research Misconduct. 65 Fed. Reg. 76260 (December 6, 2000).
- B. VA Handbook 0700. VA Administrative Investigations Handbook.
- C. VA Handbook 5021. Employee/Management Relations.
- D. Title 5 U.S.C. Section 1201 Notes, et seq. Whistleblower Protection Act of 1989.
- E. Title 38 CFR Part 44. Government wide Debarment and Suspension (Nonprocurement).
- F. Title 38 CFR §§ 1.200 through 1.205. Referrals of Information Regarding Criminal Violations.

18. FOLLOW-UP RESPONSIBILITY: ACOS for Research and Development.

19. RESCISSION: None

20. REVIEW DATE: Every three years



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