



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
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SOP: Research Misconduct

PURPOSE

The purpose of this SOP is to establish procedures for reporting, investigating and resolving allegations of research misconduct at the Jesse Brown VA Medical Center.

POLICY

Research misconduct by research staff or other personnel associated with the Research Program at Jesse Brown VAMC is strictly prohibited. The JBVAMC is committed to conducting all research activities with integrity and with adherence to scientifically sound practices and ethical principles. In addition, the Research Program at this facility conforms to Federal Policy on Research Misconduct as codified at 65 Federal Register 76260 (December 6, 2000). All allegations of research misconduct will require appropriate reporting, inquiry and/or investigation, as required by VHA Handbooks 1058.01 and 1058.2.

BACKGROUND

a. The procedures in this SOP 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, Jesse Brown VAMC 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, JBVAMC 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 SOP has been created for the administrative efficiency of JBVAMC 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.** JBVAMC 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. Accordingly, VHA Handbook 1058.2 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 VHA Handbook 1058.2, 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.

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.

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 are not covered by VHA Handbook 1058.2. 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 subpar. 12a and VA Handbook 0700). **NOTE:** *If a consolidated administrative investigation is convened, the investigation procedures must be consistent with the specifications of VHA Handbook 1058.2 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 VHA Handbook 1058.2.

e. If oversight of a research protocol falls within another entity(ies)' jurisdiction in addition to that of VA, primary responsibility for reviewing a misconduct allegation concerning that research is to be determined according to subparagraph 12c VHA

handbook 1058.2.

f. Procedures for determining appropriate corrective actions are set forth in paragraph 18 VHA handbook 1058.2. Procedures for taking disciplinary or adverse actions (e.g., admonishment, reprimand, suspension, transfer, reduction in grade and basic pay, and discharge) are treated separately (see VA Handbook 5021).

g. Although VHA handbook 1058.2 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 (see subpar. 12e[1]). **NOTE:** *VHA policy regarding patient safety is set forth at VHA Handbook 1050.1.*

DEFINITIONS

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.

Debarment: Debarment is an action taken by the VA debaring 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 VHA Handbook 1058.2, the debaring official is VA's Under Secretary for Health.* A debarment by VA has government-wide effect, unless a specific exception is granted.

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

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.

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.

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

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.

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.

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

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.

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 3. 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.

Research Integrity Officer (RIO): The RIO is the appointed official at each VA facility who is responsible for receiving and coordinating reviews of formal allegations of research misconduct.

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.

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.

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.

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 VHA Handbook 1058.2, the suspending official is the Under Secretary for Health.*

VA Medical Center: A VA medical center is a local VA medical facility or VA Health Care System comprising part of VA's national health care system.

VA Medical Center Director: The VA medical center Director is the Chief Executive of a VA medical center or Health Care System.

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.

Veterans Integrated Service Network (VISN) Director:

The VISN Director is the head of a designated regional service within the VA medical system. Each VA medical center belongs to a geographically-determined VISN and reports to the Director of that service. **NOTE:** For purposes of this Handbook, “VISN Director” means the VISN Director, or designee.

THE OFFICE OF RESEARCH OVERSIGHT (ORO) (10R)

ORO (10R) serves as the primary VHA office that advises the Under Secretary for Health on all compliance matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and research safety. ORO Central Office oversees VHA’s research misconduct program in general and reviews all misconduct cases adjudicated by the VISN Directors. An ORO ad hoc committee may conduct investigations in exceptional cases (see subpars. 12d(2) and 17b[2] VHA handbook 1058.2). If at any time in its oversight of a research misconduct case ORO determines that an allegation does not fall within the scope of this Handbook (see par. 4) or fails to meet the required threshold (see subpar. 1 3e VHA Handbook 1058.2), it may dismiss the case.

RESEARCH INTEGRITY OFFICER (RIO)

JBVAMC Director designates a RIO position responsible for overseeing misconduct allegations at JBVAMC. Currently ACOS R&D is appointed as Acting 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 and Development, Research Coordinator, Research and Development Committee Chairperson, or another individual within the research program who has sufficient institutional authority and experience to be able to fulfill the required duties outlined herein.

RESPONSIBILITIES OF RIO:

(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 VHA Handbook

1058.2, 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 SOP 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.

RIO 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.

RESPONSIBILITIES OF 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 Handbook.*

RESPONSIBILITIES OF 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 SOP. 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 that finding and proposed corrective actions according to paragraph 19 VHA handbook 1058.2.

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.

PRIVACY AND CONFIDENTIALITY RESPONSIBILITIES

The privacy of all subjects 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.

RECORD RETENTION AND ACCESS RESPONSIBILITIES

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 local 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 (see par. 6 VHA handbook 1058.2);
- (2) The case is terminated after an Inquiry (see subpar. 14g VHA handbook 1058.2);
- (3) The VISN Director does not find research misconduct, and ORO reviews and provides notification of that outcome (see subpar. 1 7c [1] VHA handbook 1058.2);
- (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 (see par. 19b VHA handbook 1058.2); 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 (see par. 19e VHA handbook 1058.2).

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.

GUIDELINES FOR 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 this Handbook 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 Handbook, 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 Handbook 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 VA) 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, VA 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. VHA, in a good faith effort to effectuate a coordinated response, must adhere to the following guidelines:

(1) For every research misconduct allegation received, the VA medical center 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 VA medical center 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 the VA medical center 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, as determined by subparagraph 12c(4). The VA medical center and other non-VA agencies or entities are encouraged to 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 as determined by subparagraph 12c(4), at least one VA employee with research experience and at least 5/8th 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. **Sequence of Review.** In cases in which VA takes the lead, as determined by subparagraph 12c(4), review of formal allegations of research misconduct must follow the sequence of steps outlined in subparagraphs 12d(1) through 12d(5). Any significant departure from this sequence of review must first be approved by ORO Central Office, must be in the interests of VA and the integrity of its research, and must ensure appropriate safeguards for Respondents and Informants, including timely notice of such changes.

(1) Inquiry and Investigation by Jesse Brown VA Medical Center. In most instances, the local VA medical center that receives a research misconduct allegation is responsible for conducting an Inquiry and, if warranted, a further Investigation. The Investigation Committee's findings and recommendations for corrective actions, if applicable, are set forth in an Investigation Report. The VA medical center Director forwards this Investigation Report with additional recommendations, if any, to the appropriate VISN Director for adjudication.

(2) Substitute Investigation by ORO Ad Hoc Committee. In exceptional cases as determined by ORO Central Office within its discretion, an ORO Ad Hoc Committee consisting of ORO staff (VA Central Office and Regional Offices) and outside experts, as needed, may investigate a misconduct allegation in lieu of the local VA medical center. Such cases may include, but are not limited to, instances in which the local VA medical center is not prepared to handle the allegation in a manner consistent with these procedures, or cannot complete an investigation for any reason, or when ORO involvement is needed to protect the public interest, including the interests of veterans

and of human research subjects. The ORO Investigation Committee may use ad hoc procedures in conducting research misconduct investigations, but all of the responsibilities and safeguards set forth in paragraphs 8 through 11 must be observed. The ORO Investigation Committee forwards its Investigation Report with recommendations for corrective actions, if applicable, to the appropriate VISN Director for adjudication, with a copy to the VA medical center Director.

(3) Adjudication by VISN Director. The appropriate VISN Director reviews the final Investigation Report and renders a decision regarding the findings and recommendations for corrective actions. The VISN Director transmits this final determination and the Investigation Report to ORO Central Office.

(4) Departmental Review. ORO Central Office reviews the case file for procedural sufficiency, consulting with the Office of Research and Development (ORD) on matters that concern VA funding. If ORO determines that the Inquiry or Investigation failed to comply with the procedures in VHA Handbook 1058.2 so as to materially affect the outcome of the case, ORO may direct the VA medical center to reopen the Investigation or convene its own Investigation.

(5) Appeal to the Under Secretary for Health. The Respondent may appeal a finding of research misconduct and proposed corrective actions (including debarment, if applicable) to the Under Secretary for Health in accordance with paragraph 19 in VHA handbook 1058.2. The Under Secretary for Health makes a ruling on the Respondent's appeal which constitutes VA's final agency action.

e. **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 VHA Handbook 1058.2 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.

f. **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 (see par. 3 1058.2 handbook), if not evident in the admission, must be established by a full Investigation.

g. **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.

h. **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 (see subpar. 1 2c 1058.2 handbook) 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.

PROCEDURES RESEARCH MISCONDUCT

STEP 1: PROCEDURES FOR ALLEGATIONS

a. Referrals:

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

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 listed in subparagraph 8d. 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 neither 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 set forth in subparagraph 13e 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 5t.

(2) The allegation is of research misconduct as defined in paragraph 3.

(3) The allegation on its face contains the elements of a finding of research misconduct as defined in paragraph 3 1058.2 handbook. 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 1 3e 1058.2 handbook, 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 found in subparagraph 1 3e 1058.2 handbook.

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 in subparagraph 1 3e 1058.2 handbook are met. The procedures in this Handbook apply in such cases.

STEP 2 PROCEDURES FOR INQUIRY

a. Applicability:

The procedures outlined in this paragraph apply whenever a VA medical center takes the lead in conducting an Inquiry, as determined by subparagraph 1 2c(4). If a non-VA agency or entity with joint jurisdiction takes the lead in conducting the Inquiry, that agency or entity's misconduct Inquiry procedures apply, consistent with subparagraph 12c(5) 1058.2 handbook.

b. Purpose.

If a research misconduct allegation meets the threshold requirements of these procedures (see subpar. 1 3e), an Inquiry must be initiated for the sole purpose of determining whether sufficient evidence exists to open a formal Investigation (see par. 15 1058.2 handbook).

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 of subparagraph 13e 1058.2 handbook , and it has been determined that the VA medical center will take lead responsibility for the Inquiry according to subparagraph 12c(4) 1058.2 handbook.

(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

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

(3) The notification specified in subparagraph 14c(2)1058.2 handbook 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 (see subpar. 14c 1058.2 handbook). 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. If review of the allegation would involve complex scientific or procedural matters, it is encouraged that an Inquiry Committee be formed to review the allegation. The VA medical center Director must charge the Committee in accordance with the purpose set forth in subparagraph 14b. The procedures in this Handbook 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 in accordance with paragraph 10 of 1058.2 handbook.

(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 (see subpar. 1 1c 1058.2 handbook).

(2) Written notice of the VA case closure must be provided to the individuals listed in subparagraph 14c(2) 1058.2 handbook. 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. In the latter case, the VA medical center Director must include in the notification letter specified in subparagraph 15c, the Director's reason for opening an Investigation despite a recommendation to terminate the case.

STEP 3 PROCEDURES FOR INVESTIGATION

a. **Applicability.** The procedures outlined in this paragraph apply whenever a VA medical center takes the lead in conducting an Investigation, as determined by subparagraph 1 2c(4) 1058.2 handbook. 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, consistent with subparagraph 1 2c(5)

1058.2 handbook.

b. Purpose. If the Inquiry results in a recommendation to open an Investigation (see subpar. 1 4h 1058.2 handbook), 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 1 4c(2) 1058.2 handbook. 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) Except as specified in subparagraph 1 5e(6) 1058.2 handbook, 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 5/8th 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 (see subpar. 12c 1058.2 handbook) 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 belongs 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 (see par. 18 1058.2 handbook). 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 VA medical center Director is to charge the Investigation Committee according to the purpose stated in subparagraph 1 5b 1058.2 handbook. The procedures in this Handbook 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 1058.2 handbook.

(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 in

accordance with paragraph 10.

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 (see par. 18 1058.2 handbook). 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 (see subpar. 4f 1058.2 handbook).

(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.

STEP 4 PROCEDURES FOR ADJUDICATION

a. **Applicability.** The procedures outlined in this paragraph apply only to the VA's adjudication of research misconduct cases. VA adjudicates every research misconduct case over which it has jurisdiction (i.e., allegations involving VA research as defined in subpar. 5t 1058.2 handbook), whether the Investigation was led by VA or by a non-VA agency or entity with concurrent jurisdiction. Non-VA agencies or entities with joint jurisdiction, if any, follow their own adjudication procedures with respect to the findings and recommendations of the Investigation Committee. VA is not bound by another agency's or entity's adjudication (see subpar. 12c[8] 1058.2 handbook).

b. **Purpose.** The purpose of an Adjudication under this Handbook is to make a VA determination, based on the recommendations from the Investigation, as to whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions.

c. **Receipt of Case.** In keeping with subparagraph 1 5h 1058.2 handbook, the appropriate VISN Director is to receive a research misconduct case from the VA medical center once its Investigation Report is completed. Prior to receipt of the case, the VISN Director should not be consulted or otherwise involved in the Inquiry or Investigation of the misconduct allegation, except to the extent that significant and extraordinary conditions require the immediate attention of the VISN Director's office.

d. **Review.** The VISN Director reviews the Investigation Report and all supporting documents before making a final adjudication of the matter.

(1) The VISN Director may request additional information from the RIO and request the Investigation Committee to examine additional issues and evidence. The VISN Director may also consult with ORO Central Office, ORD, and the Office of the General Counsel (OGC) in reviewing the case.

(2) If the VISN Director has an actual or apparent conflict of interest that cannot be resolved in adjudicating a case, another VA official must be appointed by ORO Central Office as an alternate Adjudicator. 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 Adjudicator's decision-making.

e. **Final Decision.** After fully reviewing the case, the VISN Director makes a decision about 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.

(1) The final decision must be consistent with the definition and elements of a finding of research misconduct, as specified in paragraph 3 1058.2 handbook.

(2) The VISN Director reviews the VA medical center Director's recommendation for disciplinary action(s), if any, and makes any appropriate modifications.

(3) The VISN Director's decision may adopt all, some, or none of the investigative findings and recommendations. Any decision contrary to the recommendations of the Investigation Committee and/or VA medical center Director must be noted, and

specific reasons for that decision must be set forth in writing and made part of the case file.

(4) The review and final decision is to be completed within **30 days** of the VISN Director's receipt of the Investigation Report.

f. **Transmittal.** When the VISN Director has made a final decision on the merits of a research misconduct case, that decision is to be transmitted to ORO Central Office along with the Investigation Report.

STEP 5 PROCEDURES FOR DEPARTMENTAL REVIEW

a. **Administrative Review.** ORO Central Office reviews the VISN Director's final determination along with the Investigation Report and any supporting evidence that ORO may request.

(1) The case is reviewed for conformance with the procedures set forth in this Handbook including, but not limited to: timeliness; objectivity; preservation of safeguards; thoroughness; and competence.

(2) If it determines that the allegation falls outside the scope or does not meet the threshold requirements of this Handbook, ORO will dismiss the case (see par. 6) 1058.2 handbook.

(3) ORO Central Office consults with ORD on all matters that concern or might affect VA funding.

(4) ORO Central Office may request further information from the VISN Director, the VA medical center RIO, the Investigation Committee, or other parties with relevant information.

b. **Disposition.** ORO disposes of the case as follows:

(1) If ORO determines that the Inquiry and Investigation and adjudication substantially adhered to the procedures set forth in this Handbook, the VISN Director's decision will be upheld.

2) If ORO determines that the Inquiry or Investigation did not substantially adhere to the procedures set forth in this Handbook so as to materially affect the outcome of the case, ORO will either request the VA medical center to reopen the Investigation using the same or different Committee or assemble an ad hoc ORO Investigation Committee (see par. 6) to conduct a new Investigation. The Investigation's findings and recommendations will be submitted to the VISN Director for a de novo adjudication according to paragraph 16 1058.2 handbook.

c. **Notification.** ORO Central Office provides written notification of the outcome to the Under Secretary for 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.

(1) If the final outcome does not result in a finding of research misconduct, the VA medical center Director will be directed to provide reasonable assistance in restoring the Respondent's reputation, according to subparagraph 9h 1058.2 handbook.

(2) If the final outcome involves a finding of research misconduct, ORO Central Office notifies the Respondent of the Respondent's opportunity to appeal the finding and proposed corrective actions according to paragraph 19 1058.2 handbook.

(3) If the final outcome involves a debarment recommendation, ORO Central Office issues a notice of proposed debarment to the Respondent on behalf of the Under Secretary for Health. Such a notice is prepared according to the requirements of 38 CFR sec. 44.805, and specifies the length and terms of the proposed debarment. A copy of 38 CFR Part 44 (Government-wide Debarment and Suspension [Non-procurement]) is to be included with the notification.

STEP 6 PROCEDURES FOR CORRECTIVE ACTIONS

a. **Considerations.** When a finding of research misconduct is made, corrective actions must be proposed and implemented as appropriate to the circumstances surrounding the misconduct. The VISN Director has wide discretion in proposing corrective actions. The following criteria may be considered in making that determination:

(1) The extent of the research misconduct (amount, duration, scope);

(2) The degree to which the misconduct was knowing, intentional, or reckless;

(3) The presence or absence of a pattern of misconduct;

(4) The consequences or possible consequences of the research misconduct (injury to research subjects, skewing of related research results, waste of VA funds, misleading funding reviewers, etc.)

(5) The Respondent's position and responsibility for the research project;

(6) The cooperation of the Respondent during the Inquiry and Investigation;
The likelihood of rehabilitation;

(8) The type of corrective actions imposed in past research misconduct cases with similar features, if any; and

(9) Any other extenuating or aggravating circumstances.

b. **Examples of Possible Corrective Actions.** The following is a non-exhaustive list of corrective actions that may be taken in response to a finding of research misconduct. The implementation of these actions may require further procedures, as specified in other VA rules, regulations, or policies. **NOTE: Disciplinary actions are treated separately (see subpar. 4J 1058.2 handbook).**

- (1) Government-wide debarment.
- (2) Removal from a particular project, or suspension or termination of an active award.
- (3) Restitution of funds or civil penalties.
- (4) Prohibition from receiving VA research funds for a period of time.
- (5) Correction or retraction of published article.
- (6) Monitoring or supervision of future work.
- (7) Required certification of data.
- (8) Required certification of sources (references and contributors).
- (9) Remedial education / mentoring

STEP 7 PROCEDURES APPEALS

a. Applicability

(1) All final VA research misconduct findings and proposed corrective actions (including debarment, if applicable), except those based upon a conviction or civil judgment, may be appealed to the Under Secretary for Health according to paragraph 19. Appeals of other related actions may be combined with the research misconduct appeal in a single proceeding at the discretion of the Under Secretary for Health.

(2) Only named Respondents may appeal a finding of research misconduct under paragraph 19. Neither the Informant nor any other party has a right to appeal an agency finding or non- finding of research misconduct.

b. Filing Period. In order to preserve the opportunity to appeal under these procedures, the Respondent must file a written appeal of the research misconduct finding or proposed corrective actions (including debarment, if applicable) within 30 days of receiving the notice of research misconduct finding (see subpar. 17c).

c. Submission. The appeal is to be sent directly to the Under Secretary for Health's office, with a copy to ORO Central Office. The Respondent's submission 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 grounds for the appeal, and any additional evidence that supports the grounds for appeal.

d. Review. The Under Secretary for Health reviews all appeals that are timely and complete (see subpar. 1 9c 1058.2 handbook).

(1) The appeal is reviewed and decided based on the documents submitted by the Respondent and ORO, and any other relevant information.

(2) The Office of the General Counsel (OGC) and other Departmental resources may be consulted for advice.

(3) All hearings in which a proposed debarment is being contested must adhere to the requirements of 38 CFR 44, Subpart H.

e. **Final Decision.** The Under Secretary for Health makes a final decision on the issues appealed by the Respondent, based on the Under Secretary for Health's review (see subpar. 1 9d).

(1) The Under Secretary for Health makes a final decision in writing. The written decision must include a justification for upholding, reversing, or modifying the VISN Director's decision. The decision must be consistent with the definition and elements of a finding of research misconduct, as specified in paragraph 3 1058.2 handbook.

(2) The Under Secretary for Health's final written decision must be made within 45 days after all final submissions, information, and findings of fact have been received, unless a good cause for extension exists.

(3) ORO Central Office forwards the Under Secretary for Health's final written decision to the Respondent, the VISN Director, the VA medical center Director, and the head of the agency or entity that has joint jurisdiction, if any.

(4) If the Under Secretary for Health reverses the finding of research misconduct, the VA medical center Director will be directed to provide reasonable assistance in restoring the Respondent's reputation to the extent deemed appropriate and within the VA medical center's authority, according to subparagraph 9h.

(5) If the final decision includes the imposition of a debarment, the notice to the Respondent must adhere to the requirements of 38 CFR Section 44.870.

(6) The Under Secretary for Health's decision constitutes VA's final agency action, except with respect to a debarment decision. At the Under Secretary for Health's discretion, the Under Secretary for Health may reconsider a debarment decision according to 38 CFR Sections 44. 875 and 44.880. No other appeals are available within VA.

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 (Non procurement).
- f. Title 38 CFR §§ 1.200 through 1.205. Referrals of Information Regarding Criminal Violations.

REVISION LOG:

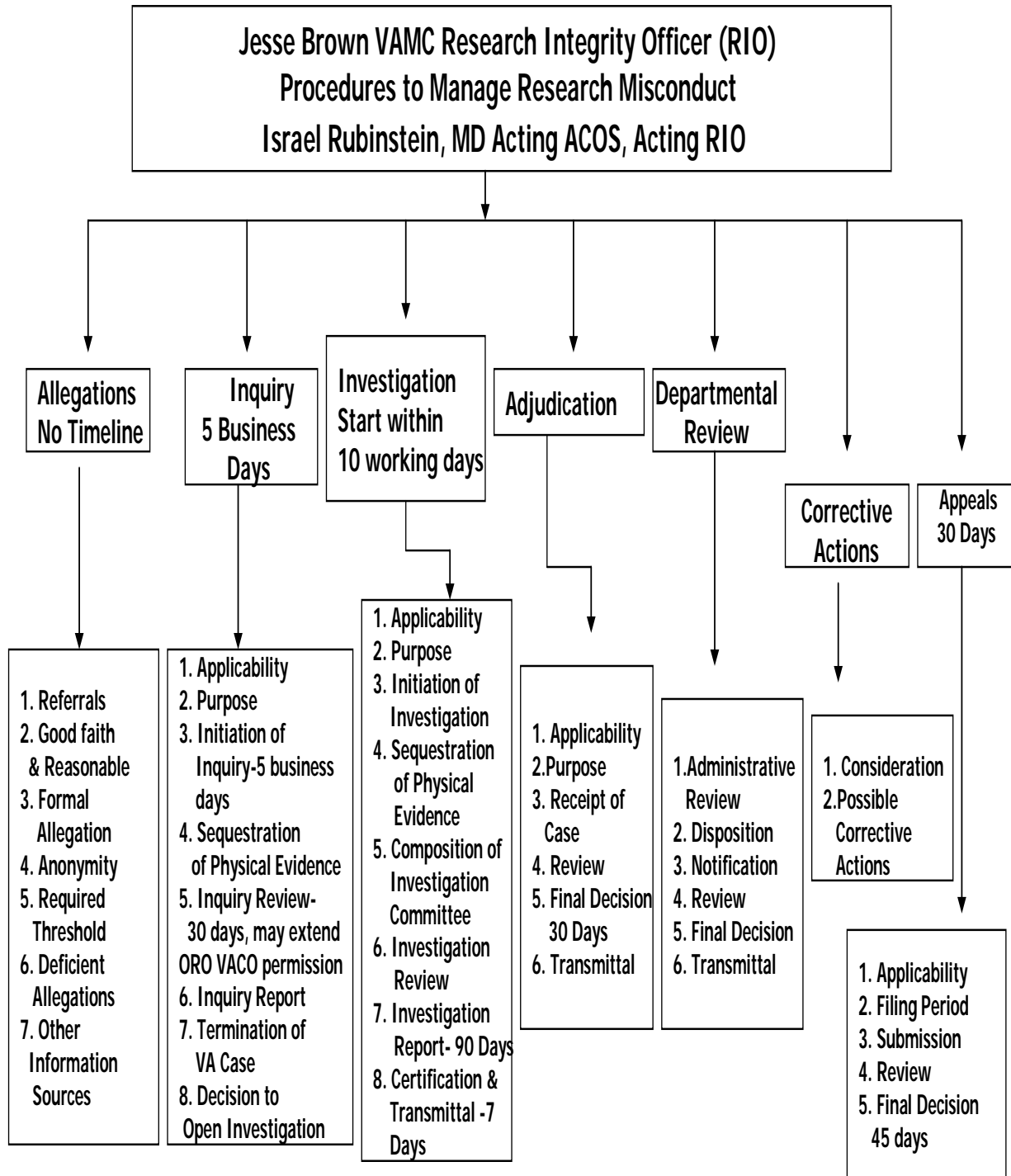
SOP: Research Misconduct

Version (#, date)	Replaces (#, date)	Summary of changes
1.1; April 20, 2009		

SOP: RESEARCH MISCONDUCT

PROCEDURES RESEARCH MISCONDUCT & TIMELINES

FLOW CHART



Date 4/23/09 Version 1.0 Salar RCO

