

IOWA CITY DEPARTMENT OF VETERANS AFFAIRS (VA) HEALTH CARE SYSTEM
Iowa City, Iowa

Medical Center Memorandum
Number 11-098

November 29, 2011
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RESEARCH MISCONDUCT

1. PURPOSE. To define the procedures and other requirements for reporting, investigating and resolving allegations of misconduct involving Department of Veterans Affairs (VA) research.
2. POLICY. The VA is committed to conducting all of its research activities with utmost integrity, adhering to scientifically sound practices as well as ethical principles. VA employees and any other individuals engaged in VA research are prohibited from committing research misconduct. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - a. Fabrication. Fabrication is making up data or results and recording or reporting them.
 - b. 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 research record.
 - c. Plagiarism. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
3. RESPONSIBILITY. This policy applies to all VA employees, including "without compensation" (WOC) employees, contractors, and Intergovernmental Personnel Agreement (IPA) personnel engaged in or requesting support for VA research. 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. Specific responsibilities are outlined below and are discussed in further detail in Attachment A.
 - a. RESEARCH INTEGRITY OFFICERS (RIO). The Associate Chief of Staff (ACOS) for Research is designated as the facility RIO responsible for overseeing misconduct allegations at that facility.
 - b. INFORMANTS. An informant is one who makes an allegation or cooperates with an Inquiry or Investigation of research misconduct. 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 a credible evidence of misconduct.
 - c. RESPONDENTS. 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. 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.

d. Research Compliance Officer (RCO). The RCO is responsible for oversight of compliance activities for the Research and Development program and serves as the primary resource person concerning compliance issues.

4. PROCEDURES. Procedures for conducting a research misconduct investigation are outlined below and discussed in further detail in Attachment B.

a. RECORD RETENTION AND ACCESS: All documents and evidence obtained or generated for a research misconduct investigation must be carefully secured and itemized.

b. JOINT JURISDICTION: Other non-VA agencies or entities may have concurrent jurisdiction over the same research project; therefore, the VA must coordinate its response to allegations of research misconduct with the relevant non-VA agencies.

c. SEQUENCE OF REVIEW:

(1) Between the time that a research misconduct allegation is filed and when it is fully resolved, VA may take interim action(s) as necessary. The Iowa City VA Health Care System must immediately notify the Office of Research Oversight (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) The local IC VAHCS that receives a research misconduct allegation is responsible for conducting an Inquiry, and if warranted, a further Investigation. The IC VAHCS Director forwards this Investigation Report with additional recommendations, if any, to the Veterans Integrated Services Network (VISN) 23 Director for adjudication.

(3) In exceptional cases as determined by ORO Central Office, an ORO Ad Hoc Committee may investigate a misconduct allegation in lieu of the local VA facility.

(4) The 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.

(5) ORO Central Office reviews the case file for procedural sufficiency. If ORO determines that the Inquiry or Investigation failed to comply with the procedures in the VHA Handbook 1058.2, ORO may direct the IC VAHCS to reopen the Investigation or convene its own Investigation.

(6) The Respondent may appeal a finding of research misconduct and proposed corrective actions to the Under Secretary for Health. The Under Secretary for Health makes a ruling on the Respondent's appeal which constitutes VA's final agency action.

d. 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.

e. 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.

f. 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.

g. ALLEGATIONS

(1) All formal allegations of research misconduct must be referred to the RIO.

(2) 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.

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

(4) 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.

(5) 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.

(a) The allegation involves VA research and meets the definition of research misconduct.

(b) 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.

(6) If the allegation fails to meet one or more of the threshold requirements listed above, the IC VAHCS Director must notify the Informant in writing, that a research misconduct case will not be opened.

(7) 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.

h. INQUIRY

(1) If a research misconduct allegation meets the threshold requirements, an Inquiry must be initiated for the sole purpose of determining whether sufficient evidence exists to open a formal Investigation.

(2) 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.

(3) If the RIO or Inquiry Committee finds that the available evidence is sufficient to justify opening an Investigation, or if the IC VAHCS Director disagrees with a recommendation to terminate the case, an Investigation must be opened.

i. INVESTIGATION

(1) 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.

(2) 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.

(3) 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.

(4) Within 7 days of receiving the final report from the Investigation Committee, the IC VAHCS Director must transmit the final Investigation Report with all supporting documents to the VISN Director to which the IC VAHCS reports.

j. ADJUDICATION

(1) The purpose of Adjudication 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.

(2) The VISN Director is to receive a research misconduct case from the IC VAHCS once its Investigation Report is completed. The VISN Director reviews the Investigation Report and all supporting documents before making a final adjudication of the matter.

(3) 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.

(4) 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.

k. DEPARTMENTAL REVIEW

(1) ORO Central Office reviews the VISN Director's final determination along with the Investigation Report and any supporting evidence that ORO may request.

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

(3) If ORO determines that the Inquiry and Investigation and adjudication substantially adhered to the procedures set forth in VHA Handbook 1058.2, the VISN Director's decision will be upheld.

l. CORRECTIVE ACTIONS. 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.

m. APPEALS

(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. Only named Respondents may appeal a

finding of research misconduct. Neither the Informant nor any other party has a right to appeal an agency finding or non-finding of research misconduct.

(2) Final Decision. The Under Secretary for Health makes a final decision in writing on the issues appealed by the Respondent, based on their review. The written decision must include a justification for upholding, reversing, or modifying the VISN Director's decision. The Under Secretary for Health's decision constitutes VA's final agency action, except with respect to a debarment decision.

5. REFERENCES. VHA Handbook 1058.2

6. RESCISSIONS. Medical Center Memorandum 08-98, Research Misconduct, dated November 14, 2008.

BARRY D. SHARP
Director

PARTICIPATING IN RESEARCH MISCONDUCT PROCEEDINGS

3. RESPONSIBILITIES. This policy applies 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. 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. Specific responsibilities are outlined below.

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

(1) The 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. The 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. If at any time in its oversight of a research misconduct case ORO determines that an allegation does not fall within the scope of the VHA Handbook 1058.2 on Research Misconduct it may dismiss the case.

b. RESEARCH INTEGRITY OFFICERS (RIOs)

(1) Each Director of a VA medical center with research involvement must designate a permanent RIO position responsible for overseeing misconduct allegations at that facility. The RIO is responsible for overseeing all aspects of research misconduct inquiries and investigations except as otherwise provided herein. The RIO must be administratively assigned to either the Associate Chief of Staff (ACOS) for Research, the Research Coordinator, RCO, 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. The RIO is specifically responsible for:

(a) 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.

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

(c) 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.

(d) 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 provisions of VHA Handbook 1058.2 Research Misconduct and this policy.

c. INFORMANTS

(1) An informant is one who makes an allegation or cooperates with an Inquiry or Investigation of research misconduct. 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 a credible evidence of misconduct.

(2) VA employees also have a responsibility to cooperate in good faith with research misconduct reviews whether led by a VA medical center or an agency/entity with joint jurisdiction.

(3) 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.

(4) 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.

(5) 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.

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

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

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

(7) 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.

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

d. RESPONDENTS

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

(2) Respondents will be given the opportunity to respond to allegations of research misconduct, the supporting evidence, proposed finding or research misconduct, and proposed corrective actions, if any. They must be promptly notified of final findings and actions.

(3) Respondents must have the opportunity to be interviewed and present evidence during the Inquiry and Investigation and to provide comments on the Investigation report. Respondents are required to cooperate in good faith with any Inquiry or Investigation conducted pursuant to this policy. Inquiries and Investigations proceed regardless of Respondents' cooperation, and misconduct determinations are based on the available evidence.

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

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

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

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

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

4. PROCEDURES. Discussed in Attachment B.

5. REFERENCES. VHA Handbook 1058.2

CONDUCTING RESEARCH MISCONDUCT INVESTIGATIONS

4. PROCEDURES

a. **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 are:

(1) 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.

(2) 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 a misconduct proceeding.

(3) 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 closed with the ORO dismisses the case, the case is terminated after an Inquiry, the VISN Director does not find research misconduct and ORO reviews and provides notification of the outcome, 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 the Respondent appeals a finding and the Under Secretary for Health makes a final decision in writing.

b. **JOINT JURISDICTION:** Other non-VA agencies or entities may have concurrent jurisdiction over the same research project, therefore, the VA must coordinate its response to allegations of research misconduct with the relevant non-VA agencies.

(1) The RIO is responsible for determining whether non-VA agencies or entities have joint jurisdiction over the underlying research. The RIO must then notify all non-VA agencies or entities that have joint jurisdiction over a research project of any misconduct allegation regarding such research. The VA medical center and the non-VA agencies or entities with joint jurisdiction are encouraged to perform a joint Inquiry, and if warranted, a joint investigation.

(2) Through informal negotiation between the VA medical center and the non-VA agencies or entities with joint jurisdiction a determination of which agency will take the lead in conducting the joint Inquiry and Investigation must be made. The applicable procedures for conducting an Inquiry and Investigation are those of the agency or entity that takes the lead.

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

(3) 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.

(4) Each agency or entity with joint 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 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.

c. SEQUENCE OF REVIEW

(1) Inquiry and Investigation by a Local VA Medical Center: 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 and outside experts, as needed, may investigate a misconduct allegation in lieu of the local VA medical center.

(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 this policy and the VHA Handbook 1058.2 Research Misconduct, 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 to the Under Secretary for Health. The Under Secretary for Health makes a ruling on the Respondent's appeal which constitutes VA's final agency action.

d. INTERIM ACTIONS.

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

(2) 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.

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

(4) 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.

e. ADMISSIONS

(1) 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.

(2) 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

(1) 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)

(1) 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.

h. ALLEGATIONS

(1) 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 a 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.

(2) 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:

(a) 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.

(b) 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.

(c) 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.

(3) Formal Allegation. If possible, allegations of research misconduct must be made in writing. 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.

(a) 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.

(b) The RIO must promptly notify the VA medical center Director of all research misconduct allegations received.

(4) 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.

(5) 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.

(a) The allegation involves VA research and meets the definition of research misconduct.

(b) 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.

(6) Deficient Allegations. If the allegation fails to meet one or more of the threshold requirements listed above, the VA medical center Director must notify the Informant in writing, that a research misconduct case will not be opened.

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

(b) 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.

(c) 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.

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

(7) 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.

i. INQUIRY

(1) Purpose. If a research misconduct allegation meets the threshold requirements, an Inquiry must be initiated for the sole purpose of determining whether sufficient evidence exists to open a formal Investigation.

(2) Initiation of Inquiry. The VA medical center Director must convene an Inquiry within five working days after a misconduct allegation is received if the allegation meets the threshold requirements, and it has been determined that the VA medical center will take lead responsibility for the Inquiry.

(3) The following persons must be provided written notification of the misconduct allegation and the opening of an Inquiry: Respondent(s), Informant, appropriate VISN Director, ORO Central Office, and the research misconduct oversight office for the agency or entity with joint jurisdiction, if any. The notification must include the name of the Respondent(s), the nature of and basis for the allegation, and the research funding involved.

(4) 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. In most cases, sequestration must take place prior to, or at the time of, notification to the Respondent.

(5) 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:

(a) The Inquiry Review 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.

(b) 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.

(c) 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.

(d) 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. The VA medical center Director must appoint an acting RIO to oversee such cases.

(e) 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.

(f) Subject-matter experts from within or outside the 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.

(g) 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.

(h) 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.

(i) Termination of VA Case. 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.

(j) 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 the reason for opening an Investigation despite a recommendation to terminate the case.

j. INVESTIGATION

(1) 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.

(2) 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 Respondent, Informant, appropriate VISN Director, ORO Central Office, and oversight office for the agency or entity with joint jurisdiction. 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.

(3) 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).

(4) 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:

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

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

(c) Except in the case of joint jurisdiction, 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.

(d) 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.

(e) 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.

(f) 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.

(g) The RIO must notify the Respondent and Informant of the Committee's membership upon selection. Within five 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.

(5) 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.

(a) 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 five working days prior to the end of the initial review period. ORO may grant an extension at its discretion.

(b) The VA medical center Director is to charge the Investigation Committee according to the purpose of an investigation. The procedures in this policy, VA Handbook 1058.2, 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.

(c) If additional Respondents or substantively new allegations are added in the course of the Investigation, notification of these additions must be given.

(d) 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.

(e) 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.

(f) 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.

(6) Investigation Report. 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. 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 seven 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.

(7) Certification and Transmittal. Within seven 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.

(a) 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.

(b) 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.

(c) 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.

k. ADJUDICATION

(1) Purpose. The purpose of Adjudication 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.

(2) Receipt of Case. 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.

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

(a) 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.

(b) 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.

(c) 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. The final decision must be consistent with the definition and elements of a finding of research misconduct. The VISN Director reviews the VA medical center Director's recommendation for disciplinary action(s), if any, and makes any appropriate modifications. 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. The review and final decision is to be completed within 30 days of the VISN Director's receipt of the Investigation Report.

(d) 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.

I. DEPARTMENTAL REVIEW

(1) 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. The case is reviewed for conformance with the procedures set forth in VHA Handbook 1058.2 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 the VHA Handbook 1058.2, ORO will dismiss the case.

(3) ORO Central Office consults with ORD on all matters that concern or might affect VA funding. ORO Central Office may also request further information from the VISN Director, the VA medical center RIO, the Investigation Committee, or other parties with relevant information.

(4) Disposition. ORO disposes of the case as follows:

(a) If ORO determines that the Inquiry and Investigation and adjudication substantially adhered to the procedures set forth in VHA Handbook 1058.2, the VISN Director's decision will be upheld.

(b) If ORO determines that the Inquiry or Investigation did not substantially adhere to the procedures set forth in this policy and VHA Handbook 1058.2 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 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 the procedures for adjudication.

(5) 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.

(a) 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.

(b) 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.

(c) 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.

m. CORRECTIVE ACTIONS

(1) 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:

- (a) The extent of the research misconduct (amount, duration, scope);
- (b) The degree to which the misconduct was knowing, intentional, or reckless;
- (c) The presence or absence of a pattern of misconduct;
- (d) 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.)
- (e) The Respondent's position and responsibility for the research project;
- (f) The cooperation of the Respondent during the Inquiry and Investigation;
- (g) The likelihood of rehabilitation;
- (h) The type of corrective actions imposed in past research misconduct cases with similar features, if any; and
- (i) Any other extenuating or aggravating circumstances.

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

n. APPEALS

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

(2) **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.

(3) **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.

(4) **Review.** The Under Secretary for Health reviews all appeals that are timely and complete.

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

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

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

(5) **Final Decision.** The Under Secretary for Health makes a final decision in writing on the issues appealed by the Respondent, based on their review. 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. 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.

(a) 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.

(b) 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.

(c) 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.

(d) 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 a debarment decision may be considered according to 38 CFR Sections 44.875 and 44.880. No other appeals are available within VA.

5. REFERENCES. VHA Handbook 1058.2