



Palo Alto Veterans Institute for Research

**POLICY AND PROCEDURES
FOR
RESPONDING TO ALLEGATIONS
OF
RESEARCH MISCONDUCT**

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POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. General Policy

The Palo Alto Veterans Institute for Research (PAVIR) is a nonprofit corporation established pursuant to Title 38 USC §7361-7366 as a flexible funding mechanism for research conducted at the VA Palo Alto Health Care System (VAPAHCS). As defined in the statute, the Department of Veterans Affairs (VA) has oversight of PAVIR operations. All PAVIR administered research is required to maintain an active VAPAHCS Research & Development approval. Such approval makes PAVIR administered research VA research which must incorporate and satisfy applicable VA rules and regulations. Specifically, VA requires that any allegations of research misconduct at a VA-affiliated NPC are handled in accordance with Veterans Health Administration (VHA) Handbook 1058.02, “Research Misconduct.” Additionally, many researchers at PAVIR and VAPAHCS hold appointments at the Leland Stanford Junior University (Stanford). The VA handbook on Research Misconduct recognizes that there are often affiliated universities which would be involved in allegations, inquiries and investigations related to research misconduct and has allowances for joint procedural jurisdiction. PAVIR, in recognition of the funding from the Department of Health and Human Services (HHS) stewarded by PAVIR, will coordinate its actions relating to allegations of research misconduct with the Office of Research Integrity (ORI) and other parties as applicable to any given circumstance.

B. Scope

PAVIR will only assume a role in allegations of research misconduct if directly associated with a PAVIR employee or a PAVIR administered project. This statement of policy and procedures is intended to carry out PAVIR’s responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with PAVIR and one or more of the following:

- (1) PHS support of biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
- (2) Applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training; or
- (3) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training including any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

Unless otherwise determined in applicable VA rules and regulations, this statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the

allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

II. Definitions

- A. Adjudication.** An adjudication is the agency determination of whether or not research misconduct occurred and what corrective actions are appropriate based on a review of the allegation, case file, and recommendations of an Investigation Committee.
- B. Allegation.** An allegation is a written or oral statement that research misconduct may have occurred, submitted in accordance with this policy.
- C. Conflict of Interest.** A conflict of interest may exist when an individual has a close familial, personal, or professional relationship with the respondent or informant, or a direct relationship with the research referenced in an allegation of research misconduct, such that the relationship creates a strong potential for biasing the individual's decision-making.
- D. Corrective Action.** A corrective action is an administrative action that is recommended and implemented based on finding(s) of research misconduct under this policy, for the purpose of ensuring the accuracy and reliability of the research record both past and future.
- E. Data.** Data means information collected, obtained, recorded, or processed while conducting or performing research. It does not include administrative or other information that has no bearing on the accuracy of the research represented in the research record.
- F. Debarment.** Debarment is an action taken by the VA Under Secretary for Health to exclude a person from participating in certain covered transactions, including exclusion from applying for, or receiving approval to conduct, VA research.
- G. Good Faith and Reasonable Allegation.** A good faith and reasonable allegation of research misconduct is an allegation that the informant honestly believes ("good faith") and is reasonable for a person in the informant's position to make in light of the readily available evidence. A research misconduct allegation is not made in good faith if it is made with reckless disregard for or willful ignorance of facts that would negate the allegation.
- H. Good Faith Cooperation.** Good faith cooperation with any of the proceedings covered by this Handbook means cooperating honestly and forthrightly with those conducting the proceedings.
- I. Informant.** An informant is the individual who submits an initial written, formal allegation of research misconduct. Witnesses who provide information in support of an informant's initial allegation are not considered informants. However, an individual who submits a substantively different written, formal allegation of research misconduct may be considered an additional informant. *NOTE: Individuals who only submit an allegation orally or anonymously are considered to be non-informant sources, and all roles and responsibilities otherwise adhering to informants under this policy will be deemed not applicable to the oral or anonymous conveyor of the allegation unless and until the individual subsequently submits an identified, written allegation. In instances where a governmental or institutional oversight body (e.g., Institutional Review Board (IRB)) rather than an individual identifies possible research misconduct, the governmental or institutional oversight body does not constitute an informant.*
- J. Inquiry.** An inquiry is the assessment of whether an allegation has substance and if an investigation is warranted.
- K. Investigation.** An investigation is the formal development of a factual record and the examination of that record leading either to a recommendation for finding(s) of research misconduct or a recommendation for no finding of research misconduct.
- L. Investigation Committee.** An Investigation Committee is the committee that is convened to conduct an investigation into allegations of research misconduct.

- M. Investigation Report.** An Investigation Report is the written report generated by an Investigation Committee that contains findings of fact, conclusions, and recommended corrective actions. Administrative attachments that accompany the Investigation Report and evidentiary exhibits cited in the Investigation Report are not considered to constitute part of the report itself.
- N. Joint Procedural Jurisdiction.** A VA and non-VA research institution (e.g., Stanford) have joint procedural jurisdiction over a common research misconduct allegation if and only if they both have independent legal authority to receive, review, and make determinations on the allegation, and to impose corrective actions for any findings of research misconduct.
- O. Preponderance of Evidence.** Preponderance of evidence means proof by information that, compared with that opposing it, leads to the conclusion that a particular matter or asserted fact is more probably true than not.
- P. Recklessness.** Committing research misconduct “recklessly” is characterized by a conscious or willful disregard for ensuring the accurate representation of the research record that a member of the relevant research community would reasonably exercise in like circumstances.
- Q. Research.** Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. 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.
- R. Research Integrity Officer (RIO).** The RIO is the appointed official who is responsible for receiving, and providing local oversight of the handling of, formal allegations of research misconduct.
- S. Research Record.** The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, case report forms and data sheets, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and written documents and materials submitted by the respondent(s) in the course of a research misconduct proceeding.
- T. Respondent(s).** Respondent(s) are the individual(s) against whom allegation(s) of research misconduct are directed and whose actions are the subject of an inquiry or investigation under this policy.
- U. Results.** Results are the scientific outcome(s) of research.
- V. Retaliation.** Retaliation is taking or threatening to take an adverse action within one’s authority against an informant or other witness in response to a good faith and reasonable allegation of research misconduct or good faith cooperation with any proceeding covered by this policy and VHA Handbook 1058.02. An adverse action may include an intentional failure to take a warranted action.
- W. VA Employee.** VA employees include individuals who hold compensated or “without compensation” (WOC) appointments, Intergovernmental Personnel Act (IPA) Agreement personnel, and Special Government Employees (SGE). PAVIR employees, not limited to, but including purposes of this policy, and in recognition of their WOC status, are considered VA employees. The majority of PAVIR PIs are VA paid employees.
- X. VA Facility.** A VA facility is any entity that is operated by VA, including but not limited to VA hospitals, medical centers, and health care systems.
- Y. VA Research.** VA research is research conducted by VA employees while on VA time, using VA resources, or on VA property including space leased to or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.
- Z. Witness.** A witness is any person who provides testimonial and/or documentary evidence as part of the proceedings covered by this policy, including but not limited to the informant and

respondent. Investigation Committee members, administrative personnel, and compliance oversight staff related to a research misconduct proceeding do not constitute “witnesses,” unless specifically acting in the capacity of a witness as defined above.

III. Research Misconduct and Evidentiary Standard

A. Research Misconduct

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. For purposes of this policy, plagiarism does **not** include authorship, credit, or intellectual property disputes among collaborators on the research study in question.
- (4) Research misconduct does **not** include honest error or differences of opinion.

B. Evidentiary Standard

To establish a finding of research misconduct, the alleged behavior must fall within the definition of research misconduct above, **and**

- (1) There must be a significant departure from accepted practices of the relevant research community; **and**
- (2) The misconduct must be committed intentionally, knowingly, or recklessly; **and**
- (3) The allegation must be proven by a **preponderance of evidence**.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All those engaged in research activities involving PAVIR will report observed, suspected, or apparent research misconduct. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the Research Integrity Officer (RIO), currently Dr. David Clark, to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the individual or allegation may be referred to other offices or officials with responsibility for resolving the problem.

B. Cooperation with Research Misconduct Proceedings

All those engaged in research activities involving PAVIR will cooperate with institutional officials in the review of allegations and the conduct of inquiries and investigations. All PAVIR researchers have an obligation to provide evidence relevant to research misconduct allegations to institutional officials.

C. Confidentiality

All individuals involved in a research misconduct proceeding (including but not limited to informants, respondents, other witnesses, the individual(s) appointed to conduct the inquiry, Investigation Committee members, consultants, legal counsel and other advisors, and other administrative personnel) must preserve the confidentiality of information reviewed during the proceeding to the extent possible consistent with a fair and thorough investigation and as allowed by law.

D. Protecting Informants, Witnesses, and Committee Members

Institutional members may not retaliate in any way against informants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, PAVIR, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

F. Interim Administrative Actions and Notification of Special Circumstances

At any time during a research misconduct proceeding, PAVIR or VA may take interim action(s) as necessary. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication.

- (1) In addition to any relevant reporting requirements under VHA Handbook 1058.01, the RIO must provide immediate notice of the following exigencies to the VA Office of Research Oversight (ORO), and after consultation with ORO, to the VA Office of Research and Development (ORD), HHS Office of Research Integrity (ORI), and other Government oversight bodies and institutions with joint oversight jurisdiction over the research misconduct allegation:
 - (a) Public health or safety is at risk, including an immediate need to protect human research subjects or animals;
 - (b) The resources (federal funds or equipment) or interests of VA and/or PHS are threatened;
 - (c) Research activities should be suspended;
 - (d) There is reasonable indication of possible violations of civil or criminal law;
 - (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding;
 - (f) There is a reasonable indication that the research misconduct proceeding might be made public prematurely; and/or
 - (g) There are other reasonable indications that the research community or public should be immediately informed of the research misconduct allegations.

- (2) If evidence of actual or possible criminal activity is discovered in connection with a research misconduct proceeding, the provisions of Title 38 Code of Federal Regulations (CFR) §§ 1.200 – 1.205 for reporting criminal matters must be followed.
- (3) At the direction of other Government oversight bodies investigating possible criminal activity (including the VA Office of Inspector General) and in consultation with ORO, and ORI, a research misconduct proceeding initiated under this policy may be temporarily suspended.
 - (a) Under such suspension, PAVIR and/or the VA facility must halt all activities initiated under this policy except that all sequestered evidence must be kept secure.
 - (b) Any evidence collected for the research misconduct proceeding must be provided to authorized officials upon request.
 - (c) All applicable time frames for completing the research misconduct proceeding once it is re-activated will be adjusted to account for the period of suspension or as otherwise advised by ORI or related funding agency.
 - (d) Any publicly available report and conclusions from an intervening Government investigation may be included as evidence in a re-activated research misconduct proceeding.
 - (e) All re-activated research misconduct proceedings must be completed per this policy, regardless of any conclusions of an intervening Government investigation, unless ORO determines that completion of the research misconduct proceeding would not be in the best interests of VA.

V. Conducting the Assessment and Inquiry

A. RIO Receipt and Processing of Allegation

The initial formal allegations of research misconduct received by the RIO will be processed according to the following procedures.

- (1) Within one (1) business day of receipt of a formal allegation of research misconduct, the RIO must notify the PAVIR CEO, VAPAHCS Director, ACOS R&D, and ORO of the allegation. All notifications to ORO must include a copy of the written allegation, if the allegation was submitted in writing.
- (2) As soon as possible, but no later than 5 business days after receipt of the allegation, the RIO must submit the following information, to the extent known, to ORO:
 - (a) The specific details about the allegation(s);
 - (b) Verification that the allegation falls within the scope of this policy; and
 - (c) An indication of whether any other institution has joint procedural jurisdiction over the allegation.
- (3) These notification requirements apply to the initial allegation(s) of research misconduct and any subsequent research misconduct allegation from any source raised at any point in a research misconduct proceeding that substantially differs from the initial allegation(s).
- (4) If it has been determined that a non-VA institution has or may have joint procedural jurisdiction over the allegation, the RIO must inform the non-VA institution of the allegation within five (5) business days after initial receipt of the allegation. At the time of notification, the RIO must begin discussions with the non-VA institution's RIO (or equivalent position) about the possibility of conducting joint proceedings (i.e., inquiry

and/or investigation) in the event that each institution independently determines that such proceedings are warranted.

B. ORO Determination about Initiating an Inquiry

Upon receipt and review of information submitted by the RIO or any other source, ORO will determine whether VAPAHCS must initiate a research misconduct inquiry or instead refer the allegation to other administrative processes as appropriate. ORO's determination should normally be completed within 10 days from receipt of all information necessary to make its determination.

C. Joint Procedural Jurisdiction

- (1) A determination about whether a non-VA institution has joint procedural jurisdiction over a research misconduct allegation should have been made no later than five (5) business days after initial receipt of the allegation.
- (2) If it is determined that a non-VA institution has joint procedural jurisdiction over a research misconduct allegation, the RIO must consult with ORO prior to making a decision to conduct or not conduct a joint inquiry or investigation with the non-VA institution. It is VA policy that in most cases in which VA and a non-VA institution have joint jurisdiction over a research misconduct allegation, it is in VA's interest to conduct a joint inquiry, and if warranted a joint investigation, with the non-VA institution to maximize procedural uniformity and minimize duplication while recognizing institutional autonomy.
- (3) If a mutual decision is made to conduct a joint proceeding, the decision about which institution will lead the proceeding should be made based on a consideration of the following:
 - (a) The institution under whose auspices the research in question was conducted.
 - (b) The institution where the research was physically conducted.
 - (c) The institution that provided greater financial, staff, and resource support for the research.
 - (d) The institution maintaining control over the evidence most relevant to the research misconduct allegation.
 - (e) The institution with legal authority to compel relevant witnesses to cooperate.
 - (f) The institution with sufficient resources, including potential committee members and administrative staff, to conduct a more timely and thorough inquiry or investigation.
 - (g) The institution with the most experience in successfully conducting research misconduct investigations.
 - (h) The extent to which the joint inquiry or investigation would address additional allegations pertinent to only one institution.
- (4) If a mutual decision is made to conduct a joint inquiry or investigation, the institution designated as the lead must document the terms of the joint proceeding and provide documentation of such terms to the RIO of the non-lead institution.
 - (a) The terms of the joint proceeding may be documented in the joint committee appointment or charge letter, and/or a separate document.
 - (b) The terms that must be specified, include, but are not limited to:
 1. Identification of the participating institutions including specification of the institution that will lead the proceeding;
 2. The purpose, scope, and applicable standard of the proceeding;

3. The applicable policies and procedures that will be followed;
 4. The names and positions of the members appointed to the joint inquiry and/or Investigation Committee, including specification of the Chair and the institution being represented by each member;
 5. The name(s) of the respondent(s), as applicable;
 6. A specific description of the allegation(s);
 7. The research funding involved, if known;
 8. The required timeframe for completion of the proceeding; and
 9. Limits, if any, of each institution's participation.
- (c) If the non-VA institution is designated as the lead, the VAPAHCS RIO must forward a copy of the document(s) specifying the terms of the joint proceeding to ORO and the Veterans Integrated Service Network (VISN) Director. A copy of the non-VA institution's policies and procedures related to research misconduct must also be forwarded to these individuals.
- (d) Each joint Inquiry and Investigation Committee must include at least one representative from each institution, including PAVIR. These representatives must have full deliberating and voting privileges regarding at least all of the research misconduct allegations within the purview of the institution they are representing.
- (e) Each joint inquiry and investigation must result in a single set of recommendations; however, a minority opinion may be noted in the corresponding reports from these proceedings.

D. Joint VA/Non-VA Inquiry Led by VA

- (1) **Purpose.** The sole purpose of an inquiry initiated pursuant to this paragraph is to provide a preliminary assessment of **readily available** evidence to determine whether a research misconduct allegation has **sufficient substance to warrant an investigation**.
- (2) **Standard.** A research misconduct allegation will be deemed to have "sufficient substance" to warrant an investigation if the inquiry determines that the **readily available** evidence would **raise a reasonable suspicion of research misconduct**.
- (3) **Procedures.** Joint VA/non-VA inquiries led by VA and convened pursuant to this paragraph must adhere to the following procedures.
 - (a) **Initiation.** The VAPAHCS Director must appoint a committee to conduct an inquiry within ten (10) business days after receiving notice of ORO's determination that an inquiry is warranted. An inquiry is considered "initiated" at the time the individual or committee is appointed by the Director.
 - (b) **Required Time Frame.** The research misconduct inquiry must be completed within 45 days from the date of initiation.
 - (c) **Appointment of the Inquiry Committee.** The VAPAHCS Director must appoint in writing the individuals to conduct the inquiry according to this paragraph.
 1. The chairperson and any other VA representatives on the committee must hold at least a 5/8 paid VA appointment at the facility; have experience conducting research including scientific familiarity with the type of research at issue in the allegation; professional stature approximately equal to or greater than that of the respondent; no unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses; and ability to collect and summarize

information according to this paragraph in an objective and timely manner.

2. At least one representative from the non-VA institution must be appointed to the joint Inquiry Committee to represent the non-VA institution's interests and perspectives.
 - a. The non-VA institution representative(s) must be nominated by the non-VA institution with concurrence by the VAPAHCS Director.
 - b. The non-VA institution representative(s) must not have any unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses.
 - c. The non-VA institution representative(s) must participate as full member(s) of the joint Inquiry Committee including making a determination about whether the allegation has sufficient substance to warrant an investigation.
 - d. The non-VA institution representative may not be appointed Chair of the committee.
 3. At least one representative must be appointed to the joint Inquiry Committee to represent PAVIR.
 4. The written appointment letter must indicate that a joint inquiry is being convened, provide the basis for the non-VA institution's joint procedural jurisdiction over the allegation, and specify that VA will lead the joint inquiry under the procedures of this policy.
 5. The letter should also:
 - a. State that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible.
 - b. An investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
 - c. Inform the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).
- (d). **Sequestration of Evidence.** As soon as possible after the RIO receives a formal allegation, the RIO must collect, sequester, and inventory all physical materials that might reasonably serve as evidence in determining the merits of the research misconduct allegation.
- (e) **Notifications.** The VAPAHCS Director must provide separate, written notifications of the inquiry to the following:
1. *The respondent.* The notification to the respondent must include: the inquiry's purpose and applicable standard; a specific description of the allegation(s) to be reviewed; the research and funding involved (if known); the name(s) and position(s) of the individual(s) appointed to conduct the inquiry; and the RIO's contact information. The notification

must either reference an applicable VHA Website where Handbook 1058.02 is posted or include an electronic or hardcopy attachment of the Handbook. If a committee is appointed to conduct the inquiry, the letter must specify the name of the individual who will serve as the committee's chairperson.

- a. If more than one respondent has been (or is subsequently) named, separate notifications to each respondent must be issued. Only the allegations specific to the notified respondent are to be included in the notification to that respondent.
 - b. If additional allegations arise during the course of an inquiry, the respondent(s) must be notified in writing of the additional allegations raised against them.
2. *The informant.* The notification to the informant must include the name of the respondent(s) against whom the informant made the allegation, a specific description of the allegation(s) submitted by the informant for which ORO determined the inquiry must be initiated, the inquiry's purpose and applicable standard, and the RIO's contact information. If more than one informant has submitted allegations that are the subject of the inquiry, separate notifications to each informant must be issued. Only the allegations submitted by the notified informant (and for which ORO determined the inquiry must be initiated) are to be included in the notification to that informant.
 3. *Others.* ORO, the relevant VISN Director, PAVIR, the non-VA institution, and ORI.
 4. The notifications to the respondent and informant must indicate that a joint inquiry is being convened, provide the basis for the non-VA institution's joint procedural jurisdiction over the allegation, specify the name and position of the the non-VA institution representative(s), and indicate that VA will lead the joint inquiry under the procedures of VHA Handbook 1058.02.
- (f) **Interviews and Review of Evidence.** The individual or committee appointed to conduct the inquiry must review the **readily available** evidence, including evidence submitted by the informant and respondent, evidence sequestered by the RIO, and testimonial evidence provided in interviews of the informant and the respondent, **only** as such evidence relates to determining whether a research misconduct allegation has **sufficient substance to warrant an investigation**.
1. If possible, both the informant and respondent must be individually interviewed as part of the inquiry. It may not be necessary to interview additional witnesses during the inquiry stage.
 2. Legal counsel or other advisors accompanying the respondent during an interview may not speak for or on behalf of the respondent. If the respondent's legal counsel is present during an interview, a representative from the VA Office of General Counsel (OGC) should, to the extent possible, either be physically present or participate in a manner that enables real time interaction (e.g., via teleconference).
 3. All inquiry interviews must be recorded. Inquiry interviews may, but are not required to, be transcribed.
 4. Subject matter experts may be consulted to aid in the review of the evidence; however, only the individual(s) appointed by the VAPAHCS

Director to conduct the inquiry may make the determination about whether the allegation has sufficient substance to warrant an investigation.

- (g) **Inquiry Memorandum.** Within the allotted time frame for completing the inquiry, the individual or committee appointed to conduct the inquiry must complete a succinct Inquiry Memorandum as follows:

1. The Inquiry Memorandum must contain the following elements: the name and position of the respondent(s); a detailed summary of the allegation(s) reviewed in the inquiry; the research and funding involved; the basis for why each allegation falls within the scope of Handbook 1058.02; a recommendation to open or not open an investigation based on the standard set forth above; a specification of which allegation(s) are recommended to be referred to an investigation, if any; a description of the evidence reviewed; and a written analysis of how the evidence supports the recommendation. If a VA-only inquiry deems a research misconduct allegation to have “sufficient substance” to warrant an investigation on the basis that a separate, non-VA inquiry determined that a research misconduct investigation was warranted, the Inquiry Memorandum also must: summarize the basis for the non-VA inquiry’s determination; indicate that the VA inquiry concurs with the non-VA inquiry’s determination; and have as an attachment a copy of the non-VA institution’s Inquiry Report.
2. The Inquiry Memorandum must be transmitted to the respondent(s) within the allotted time frame for conducting an inquiry (i.e., within 45 calendar days after initiation of the inquiry unless a deadline extension for completing the inquiry has been granted). The respondent must be afforded no less than five (5) business days from receipt of the Inquiry Memorandum to provide any comments in writing. Any comments submitted must be attached to the Inquiry Memorandum.
3. If requested, the sections of the Inquiry Memorandum that relate to the informant’s allegation(s), and only such sections, are to be made available to the informant solely for informational purposes.
4. The joint Inquiry Memorandum must indicate that it represents a joint report of VAPAHCS and the non-VA institution, provide the basis for the non-VA institution’s joint procedural jurisdiction over the allegation, and specify that VA led the joint inquiry under the procedures of Handbook 1058.02.
5. The joint Inquiry Memorandum and submitted comments, if any, from the respondent, must be transmitted to the non-VA institution within five (5) business days of the deadline for receipt of the respondent’s comments. If the non-VA institution requests copies of evidentiary exhibits cited in the Inquiry Memorandum, copies of the exhibits may be provided to the extent permitted by policy and law.

E. Joint VA/Non-VA Inquiry Led by a Non-VA Institution

The Purpose and Standard of a joint VA/Non-VA Inquiry led by a non-VA institution are the same as those led by VA.

- (1) **Procedures.** Joint VA/non-VA inquiries led by the non-VA institution must adhere to the non-VA institution's research misconduct inquiry procedures, **except that:**
- (a) In no case will the research misconduct procedures depart from the "Guidelines for Fair and Timely Procedures" set forth in the *Federal Policy on Research Misconduct* at 65 Federal Register 76260.
 - (b) Prior to initiation of the joint inquiry, the non-VA institution must provide written documentation of the terms of the proposed joint inquiry to the VAPAHCS RIO.
 - 1. The non-VA institution's policies and procedures related to research misconduct also must be provided to the VAPAHCS RIO.
 - 2. The VAPAHCS RIO must forward the foregoing documentation and policies and procedures to ORO; PAVIR CEO, and the VISN Director.
 - (c) VA, including ORO, and the non-VA institution may agree to modify the non-VA institution's procedures to incorporate specific elements of Handbook 1058.02's procedures as a condition of VA participating in a joint inquiry led by the non-VA institution. All modifications must be effected as early in the process as possible, timely notice of modifications deemed to be substantive by either ORO or the non-VA institution must be provided to the respondent, and the Inquiry Report must summarize all substantive procedural modifications.
 - (d) At least one representative from VAPAHCS and PAVIR must be appointed to the joint Inquiry Committee to represent VA's interests and perspectives. The VAPAHCS and PAVIR representation may be assigned to one person.
 - 1. The VA representative(s) must be nominated by the VAPAHCS Director with concurrence by the non-VA institution. At least one VA representative must hold a 5/8 or greater paid appointment at the VA facility and have experience conducting research.
 - 2. The VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses.
 - 3. The VA representative(s) must participate as full member(s) of the joint Inquiry Committee including making a determination about whether the allegation has sufficient substance to warrant an investigation.
 - (e) If at any point ORO determines that VA's interests are not being served by continued participation in the joint inquiry, it may terminate VA's participation and require the initiation of a VA-only inquiry.
 - (f) A copy of the Inquiry Memorandum (or its equivalent) and submitted comments, if any, from the respondent, must be transmitted to the VAPAHCS Director and PAVIR CEO within five (5) business days of issuance of the report or five (5) business days of the deadline for receipt of the respondent's comments, if any, whichever is later.

F. VA Disposition of the Inquiry Memorandum

- (1) The Inquiry Memorandum, attachments, and evidentiary exhibits must be forwarded to the VAPAHCS Director, PAVIR CEO and ORO.
- (a) If the Inquiry Memorandum recommends that an investigation be opened, an investigation must be convened according to this policy. Within 30 calendar days of the decision that an investigation is warranted, the RIO will provide ORI with

the written decision and a copy of the inquiry report. The RIO must provide the following information to ORI upon request:

1. The institutional policies and procedures under which the inquiry was conducted;
 2. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
 3. The charges to be considered in the investigation.
- (b) If the Inquiry Memorandum recommends that an investigation not be opened for any or all of the allegation(s), the VAPAHCS Director or ORO or PAVIR may nonetheless require that an investigation be convened according to VA policy. Such a decision by the VAPAHCS Director, or ORO is within their full discretion insofar as that decision is not inconsistent with any other part of Handbook 1058.02. The justification for convening an investigation in spite of a contrary recommendation by the inquiry must be documented in writing and retained according to the applicable records control schedule.
- (c) If the Inquiry Memorandum recommends that an investigation not be opened and both the VAPAHCS Director and ORO concur with that recommendation, the research misconduct case is to be terminated.
1. The VAPAHCS Director must provide written notification of VA's case closure to the respondent, informant, ORO, PAVIR CEO, VISN Director and the non-VA institution.
 2. PAVIR and the VA facility leadership must provide reasonable assistance in restoring the respondent's reputation.
 3. The informant may file a subsequent allegation of research misconduct, but only if the informant submits substantively new allegation(s) or evidence.
 4. The RIO must provide to ORI upon request the information listed at **V.F(1)(a)**.
 5. The RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

VI. Conducting the Investigation

A. Joint VA/Non-VA Investigation Led by VA

- (1) **Purpose.** The purpose of an investigation convened pursuant to this paragraph is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, and make recommended findings about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.
- (2) **Procedures.** Joint VA/non-VA investigations led by VA and convened pursuant to this paragraph must adhere to the following procedures.
 - (a) **Convocation.** The VAPAHCS Director must convene a joint investigation of all research misconduct allegations forwarded for investigation by issuing a charge letter. The charge letter must be issued within ten (10) business days of the Director's receipt of an Inquiry Memorandum recommending that an Investigation be opened. If the Inquiry Memorandum recommended that an

investigation not be opened and the Director or ORO do not concur with the recommendation, the charge letter must be issued within ten (10) business days of either the Director's or ORO's decision to require an investigation.

- (b) **Multiple Respondents.** If more than one respondent is named, the VAPAHCS Director must decide, within ten (10) business days of receipt of the Inquiry Memorandum (or subsequent addition of a respondent), whether to convene one investigation for all respondents or convene separate investigations for each respondent.
1. If substantially the same allegations are lodged against all respondents (e.g., involving the same data, figures, or publication), a single investigation should be convened. If a number of separate and distinct allegations are lodged against the individual respondents, the Director may consider convening separate investigations.
 2. In determining whether to convene a single investigation versus multiple investigations for more than one respondent, the VAPAHCS Director with assistance of the RIO and ORO must consider which option would:
 - a. Best preserve the privacy of affected parties;
 - b. Be the most efficient use of resources; and
 - c. Most effectively resolve the allegations of research misconduct.
 3. If separate investigations are convened against individual respondents, the procedures in this paragraph will apply separately to each investigation, including separate charge letters, separate Investigation Committees, separate case files, and separate Investigation Reports. No committee member of one investigation may be appointed as a committee member of another on-going investigation. The RIO may oversee multiple, ongoing investigations, but must maintain confidentiality of the information for each separate investigation.
- (c) **Required Time Frame.** The research misconduct investigation must be completed within 120 days from the investigation's initiation.
1. All investigation requirements must be completed within the 120 day time frame including: providing OGC, ORO, the informant(s) and respondent(s) with the opportunity to review and submit comments on the draft Investigation Report (or parts thereof); receiving and incorporating their comments as appropriate; and submission of the final Investigation Report to the VAPAHCS Director.
 2. The addition of new allegations and/or respondents during the course of an investigation does not automatically change the original time frame for completion of the investigation. However, the VAPAHCS Director may request an extension if necessary.
 3. If an extension of the time frame is required, the VAPAHCS Director must submit a written request for extension to ORO as early as possible but at least five (5) business days prior to the deadline for completing the investigation, providing a justification for the extension and a proposed extension period. ORO may grant an extension at its discretion.
- (d) **Director's Charge Letter; Investigation Committee Appointment.** As the Convening Authority, the VAPAHCS Director must issue a charge letter in accordance with the following requirements.
1. The Director must appoint an Investigation Committee of between three (3) to five (5) employees of the VA facility who have the ability to review,

analyze, and form conclusions about relevant evidence according to this paragraph in an objective and timely manner.

- a. The composition of the Investigation Committee should preferably be an odd number so that any disagreements about ultimate recommendations may be resolved by a majority vote.
 - b. As determined by the VAPAHCS Director, the committee must include at least one individual who has scientific familiarity with the type of research at issue in the allegation(s) and one individual (the same or different) who has experience in conducting an administrative investigation. Members appointed to the committee must not have any unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses.
 - c. The committee must include at least one individual who represents PAVIR (the same or different from other individuals).
 - d. The Director must designate one member to serve as the chairperson of the Investigation Committee. The chairperson must hold at least a 5/8 paid appointment at VAPAHCS, have experience conducting research, and have a professional stature approximately equal to or greater than that of the respondent(s).
 - e. The RIO may not be appointed as a member of the Investigation Committee, but must provide administrative and management support to the committee.
 - f. With the exception of the RIO, individuals appointed to conduct the inquiry may also be appointed as members of the Investigation Committee.
 - g. If the VAPAHCS Director is unable to identify enough qualified individuals from within the VA facility to comprise the minimum number of three (3) Investigation Committee members, otherwise qualified candidate(s) must be appointed from another VA facility within the same VISN, subject to the agreement of the other VA facility's Director.
2. The Director's charge letter must include the names and positions of the members appointed to the Investigation Committee including specification of the Chair, the name of the respondent(s), a specific description of the allegation(s) to be reviewed in the investigation, the research and funding involved (to the extent known), the purpose and evidentiary standard of the investigation, the required time frame for completion of the investigation, and the RIO's contact information.
 3. The Director's charge letter must specify that the investigation must be conducted in accordance with VHA Handbook 1058.02, that the Investigation Report must be in the standard VA format, and that the Investigation Committee must make recommended findings about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.
 4. If additional allegations of research misconduct arise during the course of the investigation, ORO must be notified and, if required, the allegations added to the scope of the investigation. When such allegations are added to the investigation, the Director's charge letter must be amended to

- include the new allegations.
5. If additional respondents are named during the course of the investigation, the Director's charge letter must be amended to include the new respondents.
 6. The Director's charge letter, and any amendments thereto, must be copied to ORO, the relevant VISN Director, PAVIR, the non-VA institution, and ORI.
 7. At least one representative from the non-VA institution must be appointed to the joint Investigation Committee to represent the non-VA institution's interests and perspectives.
 - a. The non-VA institution representative(s) must be nominated by the non-VA institution with concurrence by the VAPAHCS Director.
 - b. The non-VA institution representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses.
 - c. The non-VA institution representative(s) must participate as full member(s) of the joint Investigation Committee including making recommended findings of research misconduct and corrective actions.
 - d. A non-VA institution representative may not be appointed as Chair of the committee.
 8. The Director's charge letter must indicate that a joint investigation is being convened, provide the basis for the non-VA institution's joint procedural jurisdiction over the allegation, include the name and position of the non-VA institution representative(s), and specify that VA will lead the joint investigation.
- (e) **Sequestration of Evidence.** To the extent not already done so and as soon as possible, the RIO must collect, sequester, and inventory all physical materials that might reasonably serve as evidence in determining the merits of the research misconduct allegation.
- (f) **Notification of Investigation.** The VAPAHCS Director must provide separate, written notifications of the investigation to the following:
1. The Respondent. The notification to the respondent must include the investigation's purpose and applicable standard, a specific description of the allegation(s) to be reviewed, the research and funding involved, the name and position of the members appointed to the Investigation Committee including specification of the Chair, and the RIO's contact information. The notification must either reference an applicable VHA Web site where Handbook 1058.02 is posted or include an electronic or hardcopy attachment of the Handbook.
 - a. If more than one respondent has been (or is subsequently) named, a separate notification to each respondent must be issued. Only the allegations specific to the notified respondent are to be included in the notification to that respondent.
 - b. The notification must offer the respondent an opportunity to object to the appointment of any committee member based on a conflict of interest. The respondent may submit a written objection within three (3) business days of receiving the notification. Any written

objection must be retained as part of the case record. The final decision to retain or replace Investigation Committee members belongs to the VAPAHCS Director. If the Director decides to replace a committee member, the charge letter must be amended to reflect the change.

2. The informant. The notification to the informant must include the name of the respondent(s) against whom the informant made the allegation, a specific description of the allegation(s) submitted by the informant to be reviewed in the investigation, the investigation's purpose and applicable standard, the name and position of the members appointed to the Investigation Committee including specification of the Chair, and the RIO's contact information.
 - a. If more than one informant has submitted allegations that are the subject of the investigation, a separate notification to each informant must be issued. Only the allegations submitted by the notified informant (and referred for investigation) are to be included in the notification to that informant.
 - b. The notification must offer the informant an opportunity to object to the appointment of any committee member based on a conflict of interest. The informant may submit a written objection within three (3) business days of receiving the notification. Any written objection must be retained as part of the case record. The final decision to retain or replace Investigation Committee members belongs to the VA facility Director. If the Director decides to replace a committee member, the charge letter must be amended to reflect the change.
3. If and when any additional allegations and/or respondents are later added to the investigation, the VAPAHCS Director must provide notification of such to the foregoing individuals.
4. In addition, the notifications to the respondent and informant must indicate that a joint investigation is being convened, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, include the name and position of the non-VA representative(s), and specify that VA will lead the joint investigation.

(g) **Committee Actions.** The following requirements must be observed by the Investigation Committee in performing its charge:

1. The appointed Chair of the Investigation Committee must provide overall management of the investigation to include setting the schedule of committee activities and delegating tasks as needed to accomplish the objectives of the charge letter. The RIO must provide administrative and management support to the Chair and the committee.
2. Meetings of the committee must be in person to the extent feasible or be conducted in a manner that allows real time interaction (e.g., video/teleconferencing, etc.).
3. Minutes of committee meetings are not required; however, a chronology of the committee's activities must be documented and made part of the case record.
4. To the extent feasible, in-person interviews of the informant, respondent, and other witnesses must be conducted with at least a majority of the

- committee physically present (i.e., not participating by teleconferencing, etc.), including the Chair.
5. All final recommendations of the Investigation Committee, including split decisions, must include the participation of all appointed members of the committee.
 6. All collection, review, and analysis of evidence by Investigation Committee members must be conducted in a manner that is timely, objective, thorough, and competent, and that upholds the safeguards afforded to individuals in the research misconduct case.
 7. The non-VA institution representative(s) must participate as full member(s) of the joint Investigation Committee including making recommended findings of research misconduct and corrective actions.
- (h) **Interviews and Review of Evidence.** The General Investigation Procedures and the procedures related to witness interviews set forth in VA Handbook 0700 must be followed unless contradicted by any of the following provisions.
1. The Investigation Committee must conduct a thorough review of all allegations specified in the Director's charge letter. This will include review of the Inquiry Memorandum and its attachments, relevant evidentiary exhibits from the inquiry, and all other collected evidence relevant to the allegations.
 2. If evidence of additional research misconduct by the respondent that differs substantively from the allegations contained in the initial charge letter comes to light during the course of an investigation, the Investigation Committee through the RIO must notify ORO and PAVIR CEO.
 - a. If ORO determines that the additional allegation may be added to the scope of the investigation, the charge letter must be amended to include the new allegation. Otherwise, the new allegation must not be added to the scope of the investigation.
 - b. To determine the extent of research misconduct, the Investigation Committee may conduct a review of those aspects of the respondent's research portfolio that are related to the research referenced in the allegation(s) being investigated. However, unless there is a reasonable suspicion of additional research misconduct, the Investigation Committee should not conduct an exhaustive review of the respondent's entire research portfolio and publications in order to pursue all instances of possible research misconduct other than that involving or related to the research referenced in the allegation(s) specified in the charge letter.
 3. All collected evidence must be organized by the RIO in an indexed investigative file as set forth in VA Handbook 0700.
 4. The informant and respondent must be individually interviewed, preferably in that order, if available.
 5. Other witnesses who the committee determines are likely able to provide relevant documentary and/or testimonial evidence must be individually interviewed if available. The informant and/or respondent may suggest that other specific witnesses be interviewed, but the final decision to interview any particular witness belongs solely to the committee.
 6. Legal counsel or other advisors accompanying the respondent during an

interview may not speak for or on behalf of the respondent. If the respondent's legal counsel is present during an interview, a representative from OGC should, to the extent possible, either be physically present or participate in a manner that enables real time interaction (e.g., via teleconference).

7. All investigation interviews must be recorded and transcribed. Transcripts must be provided to the respective interviewees for correction, and included in the case record.
 8. Subject matter experts from within or outside VA selected by the Investigation Committee may be consulted to aid in the review of the evidence and provide opinions. However, only the appointed Investigation Committee is authorized to make the recommended findings in the Investigation Report.
 9. After fully reviewing and analyzing all of the relevant evidence and testimony that are reasonably available, the Investigation Committee must formulate recommendations for each allegation about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.
 10. Committee recommendations should be reached by consensus where possible. If consensus cannot be reached on one or more of the recommendations, a majority vote will determine the committee's final recommendation.
 11. The committee may not make any recommended conclusions about research impropriety or noncompliance other than research misconduct. However, the committee may make findings of fact regarding research noncompliance or impropriety but only insofar as such findings of fact are relevant to conclusions about research misconduct. Similarly, the committee may not recommend corrective actions for research impropriety or noncompliance other than research misconduct; however, the committee may recommend that identified noncompliance issues be referred to other appropriate VA entities and /or PAVIR for resolution.
 12. Recommendations of corrective actions, if any, must be appropriate and within VA's authority to implement.
- (i) **Joint Investigation Report.** Within the allotted time frame for completing the investigation, the Investigation Committee must complete an Investigation Report.
1. The Investigation Report must contain the following elements: the name and position of the respondent(s); a detailed summary of the allegation(s); and the research and funding involved. For each allegation, the Investigation Report must indicate:
 - a. The basis for why the allegation falls within the scope of Handbook 1058.02;
 - b. Recommended findings about whether and to what extent research misconduct has occurred, and who is responsible;
 - c. The evidence reviewed;
 - d. How the preponderance of the evidence supports a recommended finding of research misconduct, or that the committee determined that there was not a preponderance of the evidence to support a finding of research misconduct;

- e. A response to any contrary evidence including but not limited to the respondent's affirmative defenses; and
 - f. What corrective actions, if any, are appropriate.
2. If the Investigation Committee recommends Government-wide debarment of the respondent, the report must specifically indicate that such a debarment is being recommended in accordance with the procedures of VHA Handbook 1058.04.
 3. The Investigation Report must be in standard VA format. An index (list) identifying the evidentiary exhibits cited in the report must be prepared and the index will be considered to be part of the report. **NOTE:** *For the purposes of Handbook 1058.02, the actual evidentiary exhibits referenced in the report are not considered to constitute part of the report itself.*
 4. A draft of the Investigation Report must be completed and transmitted to ORO and OGC for review at least 60 days prior to the end of the allotted time frame for completing the investigation. If requested, administrative attachments to the report and cited evidentiary exhibits must be transmitted to ORO and/or OGC. **NOTE:** *Unless an extension has been granted, the time frame for completing a research misconduct investigation is 120 days. Thus, in the absence of an extension, the draft report must be transmitted to ORO and OGC within 60 days of the date the investigation was "initiated."* ORO and OGC will provide procedural comments, if any, on the draft report within 15 days of receipt. Upon receipt and consideration of the responses to the draft report, the Investigation Committee must revise the draft report, as appropriate, prior to sending it to the respondent and making it available to the informant for review.
 5. A draft of the Investigation Report must be transmitted to the respondent at least 40 days prior to the end of the allotted time frame for completing the investigation. **NOTE:** *Unless an extension has been granted, the time frame for completing a research misconduct investigation is 120 days. Thus, in the absence of an extension, the draft report must be transmitted to the respondent within 80 days of the date the investigation was "initiated."* The respondent must be afforded no less than 30 days from receipt of the draft report to provide any comments in writing. Upon receipt of the draft Investigation Report, respondents must be given reasonable access, as determined by the RIO, to all sequestered evidence supporting the proposed findings of research misconduct and proposed corrective actions, if any, for the purpose of preparing comments to the draft report.
 6. At the time the draft Investigation Report is transmitted to the respondent, the informant must be notified of the opportunity to review solely those sections of the draft report that relate to the informant's allegation(s). Reasonable access (e.g., timing, frequency, etc.) to review the draft report will be determined by the RIO. The informant must be afforded no less than 30 days from receipt of the notification to provide any comments in writing.
 7. Upon receipt and consideration of any responses to the draft report by the respondent and informant, the Investigation Committee must amend the report as appropriate, finalize the report, and attach the full responses of

- the respondent and informant, if any, to the final report.
8. All recommendations that are not reached by consensus must indicate the number of committee members in favor of (majority) and the number opposed to (minority) the final recommendation. At the Chair's discretion, the final report may include a synopsis of the minority viewpoint.
 9. The final Investigation Report must be signed and dated by all members of the committee.
 10. The final Investigation Report and accompanying attachments and exhibits must be transmitted to the VAPAHCS Director and PAVIR CEO within the allotted time frame for completing the investigation.
 11. The joint Investigation Report must indicate that it represents a joint report of VAPAHCS and the non-VA institution, provide the basis for the non-VA institution's joint procedural jurisdiction over the allegation, and specify that VA led the joint investigation under the procedures of Handbook 1058.02.
 12. The final Investigation Report and administrative attachments that accompany the report, including comments on the draft report if submitted by the respondent and/or informant, must be transmitted to the non-VA institution within five (5) business days of issuance of the report. If the non-VA institution requests copies of evidentiary exhibits cited in the final Investigation Report, copies of the exhibits may be provided to the extent permitted by policy and law.

B. Joint VA/Non-VA Investigation Led by Non-VA Institution

The Purpose and Standard of a joint VA/Non-VA Investigation led by the non-VA institution are the same as those led by VA.

- (1) **Procedures.** Joint VA/non-VA investigations led by the non-VA institution must adhere to the non-VA institution's research misconduct inquiry procedures, **except that:**
 - (a) In no case will the research misconduct procedures depart from the "Guidelines for Fair and Timely Procedures" set forth in the *Federal Policy on Research Misconduct* at 65 Federal Register 76260.
 - (b) Prior to initiation of the joint investigation, the non-VA institution must provide written documentation of the terms of the proposed joint investigation to the VAPAHCS RIO.
 1. The non-VA institution's policies and procedures related to research misconduct also must be provided to the VAPAHCS RIO.
 2. The VAPAHCS RIO must forward the foregoing documentation and policies and procedures to ORO and the VISN Director.
 - (c) VA, including ORO, and the non-VA institution may agree to modify the non-VA institution's procedures to incorporate specific elements of Handbook 1058.02's procedures as a condition of VA participating in a joint investigation led by the non-VA institution. All modifications must be effected as early in the process as possible, timely notice of modifications deemed to be substantive by either ORO or the non-VA institution must be provided to the respondent, and the Investigation Report must summarize all substantive procedural modifications.

- (d) At least one representative from VAPAHCS must be appointed to the joint Investigation Committee to represent VA's interests and perspectives.
 - 1. The VA representative(s) must be nominated by the VAPAHCS Director with concurrence by the non-VA institution. At least one VA representative must hold a 5/8 or greater paid appointment at the VA facility and have experience conducting research.
 - 2. The VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest with respect to the research in question, the respondent, the informant, or other key witnesses.
 - 3. The VA representative(s) must participate as full member(s) of the joint Investigation Committee including making recommended findings of research misconduct and corrective actions.
- (e) If at any point ORO determines that VA's interests are not being served by continued participation in the joint investigation, it may terminate VA's participation and require the initiation of a VA-only investigation.
- (f) A copy of the final Investigation Report and submitted comments, if any, from the respondent, must be transmitted to the VAPAHCS Director and PAVIR CEO within five (5) business days of issuance of the report or five (5) business days of the deadline for receipt of the respondent's comments, if any, whichever is later.

C. Disposition of the Investigation Report

- (1) **VAPAHCS Director Certification.** Within ten (10) business days of receiving a research misconduct Investigation Report, the VAPAHCS Director must certify completion of the investigation on behalf of VA. Within the 10-business day time frame,
 - (a) The VAPAHCS Director must review the Investigation Report.
 - (b) The VAPAHCS Director must include with the certificate of completion a concurrence or non-concurrence with each of the Investigation Report's recommended findings and corrective actions, may make additional recommended findings and corrective actions, and must provide a written rationale for each non-concurrence and added recommendation. *NOTE: For joint investigations led by the non-VA institution, the VAPAHCS Director must only provide concurrence or non-concurrence with recommended findings and corrective actions that fall within the scope of Handbook 1058.02.*
 - (c) If the VAPAHCS Director decides to impose disciplinary or adverse actions on the basis of the findings of the Investigation Committee, those actions must be imposed in accordance with all policies and procedures applicable to such actions.
 - (d) The VAPAHCS Director must transmit to ORO and PAVIR CEO the certificate of completion and two copies of the Investigation Report with administrative attachments and evidentiary exhibits appended to each copy of the report. PAVIR must retain at least one copy of the Investigation Report with appended evidentiary exhibits and attachments in accordance with the relevant records control schedule.

VII. VISN Director Adjudication

A. Applicability

VA adjudicates every research misconduct allegation investigated in accordance with the scope of Handbook 1058.02, including VA-only investigations and joint investigations whether led by VA or by a non-VA institution. VA is not bound by any other institution or funding agency's adjudication.

B. Decision Memorandum

The VISN Director must issue a written decision as to whether research misconduct occurred; and if so, a decision as to the type and extent of misconduct, the responsible individual(s), and the appropriate corrective actions.

C. Disposition

The VISN Director must transmit the final decision memorandum to ORO. ORO must provide written notification of the findings and corrective actions to the VAPAHCS Director. A copy of the VISN Director's decision memorandum must accompany ORO's notification to the VAPAHCS Director. To the extent not already provided by ORO, the VAPAHCS Director must provide a copy of ORO's written notification of the findings and corrective actions to any non-VA entity with joint procedural jurisdiction over the allegation (e.g., Stanford); PAVIR, and any non-VA funding source administered by an institution other than PAVIR if such notification is required by applicable regulation or policy. PAVIR will seek ORI advice to communicate finding to funding agencies or other parties as appropriate.

PAVIR must retain at least one copy of the final disposition memorandum and ORO communications in accordance with the relevant records control schedule.

VIII. Appeal and Debarment Proceedings

A. Applicability

Only named respondents may appeal findings of research misconduct and corrective actions under this policy. Neither the informant nor any party other than the respondent has a right to appeal a finding or non-finding of research misconduct.

B. Debarment Recommendations

If the VISN Director recommended a Governmentwide debarment, the procedures for issuing and contesting a proposed debarment in VHA Handbook 1058.04 are to be followed. PAVIR will liaise as necessary with ORI.

C. All Other Research Misconduct Appeals

Appeals of research misconduct findings and corrective actions must adhere to the following procedures:

- (1) **Submission of Appeal.** To preserve the opportunity to appeal under this paragraph, the respondent must file a written appeal of the research misconduct finding(s) and/or

- corrective action(s) within 30 days of receiving notification of research misconduct finding.
- (a) The respondent's written appeal to the Under Secretary for Health must be submitted to ORO for delivery to the Under Secretary. The appeal must be sent via certified mail or equivalent (i.e., with a verified method of delivery).
 - (b) The respondent's submission must include the notice of research misconduct finding, the final Investigation Report, the precise research misconduct findings and/or corrective actions that are being appealed, a statement of the grounds for the appeal, and any additional evidence that supports the grounds for appeal.
 - (c) Three complete, collated copies of the appeal must be submitted.
 - (d) No in-person hearings are provided for under this paragraph.
- (2) **Review of Appeal.** The Under Secretary for Health or designee will review all appeals that are timely and complete.
- (a) The Under Secretary or designee will review all documents submitted by the respondent by the required deadline, documents submitted by ORO, and any other relevant information.
 - (b) OGC, ORO, and other Department of Veterans Affairs resources may be consulted for advice.
 - (c) The Under Secretary may request additional information or clarifications from the Investigation Committee, VAPAHCS personnel, and/or the VISN Director. The Under Secretary may also request that the Investigation Committee provide additional analysis.
- (3) **Final Agency Decision.** The Under Secretary for Health must make a final decision on the issues appealed by the respondent.
- (a) The Under Secretary for Health must issue a written Final Agency Decision.
 - (b) The Final Agency Decision must include a justification for upholding, reversing, or modifying the VISN Director's Decision Memorandum. *NOTE: An appeal of a finding of research misconduct on the basis of noncompliance with the procedures set forth in Handbook 1058.02 will not be grounds for reversing the finding unless the magnitude and consequence of such noncompliance are determined by the Under Secretary to have materially affected the outcome of the case.*
 - (c) The Final Agency Decision must be consistent with the definition and evidentiary standard in Handbook 1058.02.
 - (d) The Under Secretary's final written decision should normally be completed within 45 days from receipt of all submissions, information, and findings of fact.
- (4) **Notifications.** ORO forwards the Final Agency Decision issued by the Under Secretary for Health to the respondent, with copies to the VISN Director, and the VAPAHCS Director.
- (a) ORO must provide written notification of the case closure to ORD and any Federal entity that has joint oversight jurisdiction over the allegation.
 - (b) To the extent not already provided by ORO, the VAPAHCS Director must provide written notification of the case closure to the informant, PAVIR, any non-VA institution with joint procedural jurisdiction over the allegation, and any non-VA funding source if such notification is required by applicable regulation or policy.
- (5) **Decision to Reverse all Findings.** If the Under Secretary for Health reverses all findings of research misconduct, leadership at PAVIR and VAPAHCS must provide reasonable assistance in restoring the respondent's reputation.

- (6) **Decision to Uphold Findings.** If the Under Secretary for Health upholds any finding(s) of research misconduct and corrective actions, the corrective actions must be implemented.
- (7) PAVIR will seek assistance from ORI for additional action if necessary.

IX. Completion of Cases; Reporting Premature Closures to ORI

A. Maintaining Records for Review by ORI

PAVIR will maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. PAVIR will notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.