Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1058.02
Transmittal Sheet
July 10, 2020

RESEARCH MISCONDUCT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes requirements for handling allegations of research misconduct involving Department of Veterans Affairs (VA) research.

2. SUMMARY OF MAJOR CHANGES: This VHA directive provides updated requirements for handling allegations of research misconduct.

3. RELATED ISSUES: VA Handbook 0700, Administrative Investigations, dated July 31, 2002; VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017; VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015; VHA Directive 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated November 14, 2019; and VHA Directive 1200, Research and Development Program, dated May 13, 2016.

4. RESPONSIBLE OFFICE: The Office of Research Oversight (10R) is responsible for the contents of this directive. Questions may be addressed at 202-632-7620.

5. RESCISSIONS: VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of July 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH

/s/ Douglas Bannerman, Ph.D.
Executive Director, Office of Research Oversight

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

This Veterans Health Administration (VHA) directive sets forth requirements for reporting, investigating, and resolving allegations of research misconduct involving Department of Veterans Affairs (VA) research. Allegations of research misconduct must be processed according to the requirements set forth in this directive. **AUTHORITY:** Title 38, United States Code (U.S.C.) § 7307 and 65 Federal Register (FR) 76260 (December 6, 2000). ***NOTE:*** *This directive is established for the administrative efficiency of VA and does not create new rights for any individual; however, individual rights or obligations that must be observed in the course of investigations may arise under other policies, regulations, laws, or governing collective bargaining agreements. See VA Handbook 0700, Administrative Investigations, dated July 31, 2002.*

2. BACKGROUND

a. VHA research misconduct policy is based on the Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy (OSTP), Executive Office of the President at 65 FR 76260, dated December 6, 2000. The OSTP policy applies to Federally funded research and proposals submitted to Federal agencies for research funding and sets forth the responsibilities of research institutions conducting such research, including VA medical facilities conducting VA research. As Federally funded research institutions, VA medical facilities, in conjunction with the Veterans Integrated Service Networks (VISNs) as specified in this directive, bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institutions.

b. The fundamental objectives of the Federal and VA policies on research misconduct are to ensure the accuracy and reliability of the research record and to maintain confidence in the research record. Therefore, these policies are limited to addressing misconduct related to the conduct and reporting of research, as distinct from misconduct that occurs in the research setting but that does not affect the integrity of the research record. For a definition of research record, see paragraph 3.v.

3. DEFINITIONS

a. **Adjudication.** An adjudication is the agency determination of whether research misconduct occurred and what corrective actions are appropriate based on a review of the allegation, case file, and recommendations of an investigation.

b. **Allegation.** An allegation is a written or oral statement that research misconduct may have occurred, submitted in accordance with this directive. See Appendix A.

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 directive, for the purpose of ensuring the accuracy and reliability of the research record both past and future. Corrective actions do not include adverse actions or disciplinary actions as defined in VA Directive 5021, Employee/Management Relations, dated April 15, 2002.

e. **Data.** For purposes of this directive, data is 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. **Fabrication.** Fabrication is making up data or results and recording or reporting them.

g. **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.

h. **Good Faith and Reasonable Allegation.** A research misconduct allegation is made in good faith and reasonable if: (1) the informant honestly believes the allegation to be true, and (2) it is an allegation that a reasonable person in the informant's position could 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.

i. **Good Faith Cooperation.** Good faith cooperation with any of the proceedings covered by this directive means cooperating honestly and forthrightly with those conducting the proceedings.

j. **Governmentwide Debarment.** Governmentwide debarment is an action taken by the Under Secretary for Health to exclude a person from participating on a Federal Governmentwide basis in the covered transactions listed in 2 C.F.R. part 180 as supplemented by 2 C.F.R. part 801, and transactions covered under the Federal Acquisition Regulation (48 C.F.R. chapter 1). A person so excluded is debarred. ***NOTE:*** *For purposes of this directive, debarment does not refer to the corrective or other actions proposed or implemented by VA that have VA-only effect (e.g., prohibition from conducting VA research and prohibition from receiving VA funding to conduct VA research).*

k. **Informant.** An informant is the individual who submits an initial written, formal allegation of research misconduct based on first-hand knowledge of facts pertinent to the allegation. See paragraph 9.a. 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 based

on first-hand knowledge of facts pertinent to the allegation may be considered an additional informant. ***NOTE:*** *Individuals who only submit an allegation orally or anonymously are non-informant sources, and all roles and responsibilities otherwise adhering to informants under this directive 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.*

l. **Inquiry.** An inquiry is the assessment of whether an allegation has substance and if an investigation is warranted. This is also known as a "preliminary inquiry" under VA Handbook 0700 and does not in itself constitute an administrative investigation under that handbook.

m. **Inquiry Report.** An Inquiry Report is the documentation of an inquiry's results that summarizes the information found and a determination of whether the research misconduct allegation(s) have sufficient substance to warrant an investigation.

n. **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. A research misconduct investigation constitutes an "administrative investigation" under VA Handbook 0700.

o. **Investigation Report.** An Investigation Report is the written report generated by an Investigation Committee that contains findings of fact, conclusions, and recommended corrective actions.

p. **Joint Jurisdiction.** For purposes of this directive, a VA and non-VA research institution (e.g., a VA medical facility's academic affiliate) have joint jurisdiction over a common research misconduct allegation if they each possess independent institutional authority to receive, review, and make determinations on the allegation. Considerations for determining jurisdiction may include but are not limited to the funding stream, institutional time and effort on the research activity, institutional approval of the protocol, and institutional affiliation listed on the publication/presentation.

q. **Plagiarism.** Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. For purposes of this directive, plagiarism does not include authorship, credit, or intellectual property disputes among collaborators on the research study in question (see paragraph 7.b.(3)).

r. **Preponderance of Evidence.** An allegation proven by a preponderance of evidence means, based on the available evidence, the allegation is considered more likely than not to be true.

s. **Reckless.** For purposes of this directive, research misconduct is committed recklessly if it 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.

t. **Research.** For purposes of this directive, 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.

u. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

v. **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, and journal articles.

w. **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 directive. See paragraph 9.b. Potential respondents include, but are not limited to, Principal Investigators (PIs), co-PIs, sub-investigators, key personnel, trainees, students, technicians, and research coordinators.

x. **Responsible VA Medical Facility.** The responsible VA medical facility is where both the research in question was approved and the respondent(s) held a VA appointment, regardless of whether the research was conducted partially or entirely off-site at another VA or non-VA facility. For allegations pertaining to unapproved VA research, research approved by multiple VA medical facilities, research involving multiple respondents employed at various VA medical facilities, and other scenarios not covered by paragraph 3.x, a responsible VA medical facility will be designated by the Office of Research Oversight (ORO) in consultation with the Director(s) of the applicable VA medical facility(ies) involved in the research referenced in the allegations. The ORO Research Misconduct Officer (ORO-RMO) will serve as the liaison for communications between the relevant VA medical facilities.

y. **Results.** Results are the scientific outcome(s) of research (as defined in paragraph 3.t.).

z. **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 directive. An adverse action may include an intentional failure to take a warranted action.

aa. **VA Employee.** For purposes of this directive, VA employees include individuals who hold compensated or without compensation (WOC) appointments, Intergovernmental Personnel Act (IPA) personnel, and Special Government Employees (SGE).

bb. **VA Research.** For purposes of this directive, VA research is research conducted by VA employees while on VA time.

cc. **Witness.** A witness is any person who provides testimonial or documentary evidence as part of the proceedings covered by this directive, including but not limited to the informant and respondent. See paragraph 9.c. 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.

4. POLICY

It is VHA policy that VA employees conduct research activities with the utmost integrity, that VA employees engaged in research are prohibited from committing research misconduct, and that VHA investigates and adjudicates allegations of research misconduct involving VA research.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Reviewing and making a Final Agency Decision on written appeals of research misconduct findings and corrective actions (see paragraphs 2.b. and 2.c of Appendix F).

(3) Deciding whether to impose Governmentwide debarments against respondents who have been found under this directive to have engaged in research misconduct and against whom such debarments are recommended in accordance with VHA Directive 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated November 14, 2019.

b. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Providing assistance to VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive, relevant standards, and applicable regulations.

(4) Determining if the VISN Director has an unmanageable conflict of interest (see paragraph 3.c. in the body of this directive and paragraph 3.a.(2). in Appendix E) as the adjudicator of a research misconduct proceeding.

(5) Appointing an alternate adjudicator if the VISN Director is found by the Assistant Under Secretary for Health for Operations to have an unmanageable conflict of interest (see paragraph 3.a.(2) of Appendix E).

c. **Executive Director, Office of Research Oversight.** The Executive Director of ORO is responsible for:

(1) Ensuring ORO's Research Misconduct Oversight Program functions effectively.

(2) Providing interpretations on the contents of this directive including:

(a) Determining at any point during a research misconduct proceeding that an allegation does not fall within the scope of this directive or does not meet the definition of research misconduct in paragraph 3.u.

(b) Preparing rulings on procedural matters, consistent with the requirements of this directive, at the Executive Director's own initiative or upon request of any person or office involved in a research misconduct proceeding at any point during the proceeding. ORO's procedural rulings will be documented and are final except that a respondent may appeal any such ruling to the Under Secretary for Health as part of an appeal of research misconduct findings or corrective actions (see paragraph 2 of Appendix F).

(c) Determining if circumstances in individual cases of alleged research misconduct dictate variation from this directive when deemed in the best interests of VA (see paragraph 8.d.). Any change from these procedures must be pre-approved by ORO and ensure fair treatment of the respondent.

(d) Providing general guidance to the appropriate VISN Director and the Under Secretary for Health regarding their responsibilities under this directive. ***NOTE:*** *ORO will not make any agency determination regarding the substance of research misconduct findings and corrective actions or appeals thereof.*

(3) Completing the responsibilities assigned to ORO in this directive or delegating the responsibilities to the ORO-RMO for completion.

d. **Research Misconduct Officer, Office of Research Oversight.** The ORO-RMO is responsible for:

(1) Overseeing the duties of ORO's Research Misconduct Oversight Program including oversight of all research misconduct allegations involving VA research.

(2) Providing review, instruction, and guidance as needed pertaining to VA medical facilities' receipt and investigation of research misconduct allegations, VISN Directors'

adjudications, and all appeals of research misconduct findings to the Under Secretary for Health.

(3) Scheduling in-person or telephone meetings with the VA medical facility Research Integrity Officer (RIO), the individual(s) appointed to conduct an inquiry, and/or the Investigation Committee to provide more in-depth instruction and guidance on the requirements contained in this directive.

(4) Providing ongoing guidance on research misconduct issues through ORO's Website and periodic teleconferences, in-person meetings, or other venues with VA medical facility RIOs. The research misconduct page of ORO's website can be accessed at https://www.va.gov/ORO/oro_research_misconduct.asp.

(5) Notifying and consulting with other offices and entities at any time if ORO has reason to believe that a research misconduct proceeding may involve that office or entity. As needed, the ORO-RMO will coordinate with other Federal agencies on behalf of VA to determine which agency/entity will serve as the lead in responding to an allegation of research misconduct, and whether any guidelines in this directive need to be modified to enable a coordinated response.

(6) Fulfilling ORO responsibilities of this directive when delegated by the Executive Director of ORO.

e. **Veterans Integrated Service Network Director.** Each VISN Director is responsible for:

(1) Ensuring that all VA medical facilities conducting research within the VISN comply with this directive.

(2) Based on the Investigation Report, making a final adjudication as to whether research misconduct occurred, and if so, the type and extent of the misconduct, the responsible individual(s), and the appropriate corrective actions.

(3) Documenting the final adjudication in a Decision Memorandum as specified in Appendix E.

(4) Reviewing any Governmentwide debarment recommendations against research misconduct respondents (see paragraph 3.d.(3) of Appendix E) and issuing a written opinion agreeing or disagreeing with the recommendation in accordance with VHA Directive 1058.04.

(5) Appointing an alternate VA medical facility within the VISN to handle research misconduct allegations if, as determined by ORO, the otherwise responsible VA medical facility is unable to complete the requirements of this directive satisfactorily with respect to a specific allegation of research misconduct. In such cases, ORO must be consulted on the specific procedures to be followed.

f. **VA Medical Facility Director.** As the Director of a VA medical facility with active research programs, the VA medical facility Director is responsible for:

(1) Overseeing a research misconduct proceeding if the Director's VA medical facility is the responsible VA medical facility as defined in paragraph 3.x. This responsibility includes initiating an inquiry and convening an investigation if and as required under this directive.

(2) Ensuring that all inquiry and investigation requirements set forth in this directive are satisfied, including but not limited to: timeliness, objectivity, preservation of safeguards, thoroughness, and competence.

(3) Appointing, in writing, an individual who is employed by that VA medical facility to serve as the VA medical facility RIO. The individual must have previous experience conducting research or providing research administrative oversight, and sufficient institutional authority to be able to fulfill the required responsibilities (see paragraph 5.g.).

(a) Examples of VA medical facility staff who may be qualified to serve as RIO include, but are not limited to, individuals serving as the Associate Chief of Staff (ACOS) for Research and Development (R&D), Deputy ACOS for R&D, Administrative Officer (AO) for R&D, or Research Compliance Officer. ***NOTE:*** *Individuals serving in administrative roles within the Research Service (e.g., ACOS for R&D) do not have an inherent conflict of interest in serving as the RIO by virtue of their position. There may be specific situations, however, where these individuals have a particular conflict of interest as defined at paragraph 3.c. See paragraph 5.f.(3)(c) for addressing such situations.*

(b) The ORO-RMO must be notified of any RIO personnel changes within 30 days.

(c) If the VA medical facility Director determines the RIO has a conflict of interest that cannot be appropriately managed with respect to the research, the respondent, the informant, or other key witnesses in a research misconduct case, the VA medical facility Director must appoint another individual to serve as acting RIO who meets the requirements of paragraph 5.f.(3) to oversee such cases.

(4) Signing written notifications to the informant (if applicable) that an inquiry will not be opened if a determination has been made that a research misconduct inquiry will not be initiated (see paragraph 4.d.(2)(c)1. of Appendix A).

(5) Appointing an individual or committee (Inquiry Committee) to conduct an inquiry within 30 business days after a determination is made that an inquiry is warranted (see paragraph 2.c.(3) of Appendices B and C).

(6) Signing separate, written notifications of the opening of an inquiry to the respondent(s), informant(s), and others as described in paragraph 2.c.(5) of Appendices B and C.

(7) Appointing an Investigation Committee, 30 days after a determination that an investigation is required, that can review, analyze, and form conclusions in an objective manner about relevant evidence according to paragraph 3.b.(4)(a) of Appendices B and C. The charge letter must be in accordance with VA Handbook 0700 and the requirements specified in paragraph 3.b.(4) of Appendices B and C.

(8) Signing separate, written notifications of the opening of an investigation to the respondent(s), informant(s) and others as described in paragraph 3.b.(6) of Appendices B and C.

(9) Making diligent efforts within the scope of the Director's authority to protect from retaliation all witnesses who cooperate in good faith with a research misconduct proceeding.

(10) Making diligent efforts within the scope of the Director's authority to protect from retaliation informants who make good faith and reasonable allegations of research misconduct.

(11) Submitting a written request to the ORO-RMO for an extension of the required timeframe to complete the proceeding providing a justification for the extension and a proposed extension period if required (see paragraphs 2.c.(2)(c) and 3.b.(3)(c) in Appendices B and C).

(12) Certifying completion of an investigation on behalf of VA within 30 days of receiving the Investigation Committee's Investigation Report and forwarding the Investigation Report with additional recommendations, if any, to the ORO-RMO (see paragraph 3.c.(1). in Appendices B, C, and D).

(13) For instances where research misconduct is not found, affording reasonable assistance to respondents in restoring their reputations to the extent that the VA medical facility Director deems appropriate, and within the scope of the VA medical facility's authority.

g. **VA Medical Facility Research Integrity Officer.** The RIO is the appointed official at each VA medical facility with an active research program who is responsible for receiving and providing local oversight of formal allegations of research misconduct. The designated RIO is responsible for:

(1) Being familiar with this directive and promoting awareness and understanding of this directive among VA medical facility employees who are engaged in research activities in their capacities as VA employees. See paragraph 11 for recommended training about research misconduct.

(2) Overseeing the VA medical facility's compliance with the provisions of this directive.

(3) Providing the informant an opportunity for a consultation with the RIO prior to submitting formal allegations (see paragraph 2 of Appendix A).

(4) Receiving and processing formal allegations of research misconduct per paragraphs 3 and 4 of Appendix A. This includes determining whether the responsible VA medical facility must initiate a research misconduct inquiry based on its review of the allegations.

(5) Serving as the primary VA medical facility liaison with the ORO-RMO for all research misconduct allegations at the VA medical facility.

(6) Serving as the primary VA medical facility liaison with the RIO (or equivalent position) of any non-VA institution with joint jurisdiction over a research misconduct allegation.

(7) Providing administrative management of, and support to, research misconduct inquiries and investigations, including but not limited to:

(a) Sending notifications from the VA medical facility Director to the individuals as specified in the appendices.

(b) Ensuring that all VA medical facility Director, Inquiry Committee, and Investigation Committee responsibilities are satisfied within the required timelines as specified in the appendices.

(c) Arranging for all necessary resources to be available for the VA medical facility's conduct of research misconduct proceedings according to this directive.

(d) Determining which evidence is relevant and sequestering relevant evidence as soon as practical and in a secure manner with a documented chain of custody, maintaining a list of numbered evidentiary exhibits, and limiting access to the evidence to authorized individuals, with supervision if required (see paragraphs 2.c.(4) and 3.b.(5) of Appendices B and C).

(e) Retaining all records of the research misconduct proceeding according to the relevant records control schedule. See paragraph 12.

(f) Organizing all collected evidence in an indexed file (see paragraphs 3.b.(8)(c) in Appendices B and C of this directive and VA Handbook 0700).

(g) Transmitting the final Investigation Report and accompanying attachments and exhibits to the VA medical facility Director and the ORO-RMO within the allotted time frame for completing the investigation.

NOTE: *The RIO may obtain assistance to carry out any of the above administrative duties but retains the responsibility to ensure they are carried out appropriately.*

h. **Chair, VA Medical Facility Inquiry Committee.** The Chair of the VA medical facility Inquiry Committee is responsible for:

(1) Conducting, in conjunction with the Inquiry Committee, a preliminary assessment of the readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation (see paragraph 2.a of Appendices B and C).

(2) Producing, in conjunction with the Inquiry Committee, an Inquiry Report in accordance with the processes outlined in paragraph 2.c.(7) of Appendices B and C.

i. **Chair, VA Medical Facility Investigation Committee.** The Chair of the VA medical facility Investigation Committee is responsible for:

(1) Providing overall management of the investigation including setting the schedule of committee activities and delegating tasks as needed to accomplish the objectives of the charge letter.

(2) Conducting, in conjunction with the Investigation Committee, a review of the allegations in accordance with the processes outlined in paragraphs 3.b.(7)-(8) of Appendices B and C.

(3) Producing, in conjunction with the Investigation Committee an Investigation Report in accordance with the processes outlined in paragraph 3.b.(9) of Appendices B and C.

6. ELEMENTS OF A RESEARCH MISCONDUCT FINDING

To establish a finding of research misconduct:

a. The alleged behavior must fall within the definition of research misconduct. Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. ***NOTE:*** *Requests for funding (e.g., VA Merit Award applications) are considered research proposals and submitting such a request is considered one example of proposing research*;

b. There must be a significant departure from accepted practices of the relevant research community. ***NOTE:*** *Per this directive, proof of fabrication, falsification, or plagiarism by a preponderance of evidence constitutes a prima facie showing of a significant departure from accepted practices of the relevant research community, defined as those engaged in VA research. The Investigation Committee, VISN Director, and Under Secretary for Health (as applicable) need not proffer additional independent evidence to establish a significant departure from accepted practices;*

c. The misconduct must be committed intentionally, knowingly, or recklessly; and

d. The allegation must be proven by a preponderance of evidence (see paragraph 3.r.). ***NOTE:*** *A higher burden of proof, such as "by clear and convincing evidence" or "beyond a reasonable doubt," is not required to establish a finding of research misconduct.*

7. APPLICABILITY

a. **Potential Respondents.** Potential respondents include:

(1) Current or former VA employees (see paragraph 3.aa.) who are alleged to have committed research misconduct in proposing, performing, or reviewing VA research, or in reporting VA research results.

(2) Individuals who are alleged to have committed research misconduct in relation to a request for VA research support (e.g., a VA Merit Award application) and who were not VA employees at the time of the request, but who become VA employees subsequent to the request.

b. **Conduct Not Covered Under This Directive.** This directive applies exclusively to allegations of research misconduct as defined in paragraph 3.u. The conduct listed in this paragraph does not fall within the scope of this directive. Such conduct that is prohibited by other statutes, regulations, or policies should be referred to the appropriate agencies for possible investigation.

(1) Forgery of research team members', administrators', or subjects' signatures, except insofar as the forgery allegedly resulted in an inaccurate representation of the research record as defined in paragraph 3.v.

(2) Omissions of data if, according to the accepted practices of the relevant research community, the research record would be considered accurately represented despite the omissions.

(3) Authorship, credit, or intellectual property disputes among contributors to a research study. ***NOTE:*** *Proposing and conducting research often involves collaboration among individuals. Many allegations of plagiarism pertain to authorship or credit disputes among collaborators or former collaborators on a research study. In many instances, collaborators are alleged to have made independent use of products (e.g., concepts, methods, descriptive language, results) of the joint effort. The ownership of such jointly developed products is often unclear, and a collaborative history often supports a presumption of implied consent for individual collaborators to use jointly developed products. For these reasons, disputes among collaborators pertaining to products resulting from prior joint efforts often are determined to involve authorship or credit disputes rather than plagiarism. (This statement is adapted from the policy on plagiarism published by the Office of Research Integrity, United States Department of Health and Human Services which is located at: https://ori.hhs.gov/ori-policy-plagiarism).*

(4) Alleged research misconduct committed by an individual who has never been a VA employee (see paragraph 3.aa.). Such allegations may be referred by the individual who is making the allegation to the relevant institution, oversight office, or journal editor for evaluation and possible investigation.

(5) An allegation of research misconduct that is not made in good faith or is unreasonable is not in and of itself an act of research misconduct. ***NOTE:*** *An Inquiry and Investigation Committee may consider evidence that an allegation was not made in good faith to inform its determinations about the informant's credibility or the underlying research misconduct allegation.*

(6) Ethical improprieties and regulatory noncompliance that occur in the VA research setting but do not fall within the definition of research misconduct at paragraph 3.u. Examples include but are not limited to: conflicts of interest, misallocation of funds, sexual harassment, discrimination, protocol violations, and breaches of human subject protection, or animal welfare requirements.

(7) Misrepresentation of information other than data or results embodying facts from scientific inquiry.

(8) Any other conduct or behavior that is not specifically covered under the definition of research misconduct at paragraph 3.u.

c. **Allegations Other Than Research Misconduct.** This directive does not apply to any allegations that do not fall within the definition of research misconduct at paragraph 3.u.

(1) If an informant makes both research misconduct and other allegations, only the research misconduct allegation(s) shall be processed according to this directive, except as permitted under paragraph 7.c.(4).

(2) Allegations other than those of research misconduct may be referred to the relevant authorities by the informant for appropriate action under other applicable policies and procedures.

(3) Evidence of improprieties or noncompliance other than research misconduct may be considered in a research misconduct proceeding if relevant but will not form the sole basis for a recommended finding of research misconduct. Any conclusions related to improprieties or noncompliance other than research misconduct will not be made as part of the proceedings under this directive except as permitted under paragraph 7.c.(4). Potential instances of impropriety or noncompliance other than research misconduct may be referred to the relevant authorities for appropriate action under applicable policies and procedures.

(4) For joint VA/non-VA proceedings led by the non-VA institution (see Appendix D), the non-VA institution under its own policies and procedures may elect to investigate both matters that fall within the definition of research misconduct at paragraph 3.u. and other noncompliance matters in the same proceeding.

8. RESEARCH MISCONDUCT PROCEEDINGS

a. **Sequence of Review.** All research misconduct proceedings subject to this directive shall follow the sequence of steps outlined below, and as further detailed in the

appendices. A flowchart of the sequence of review is located at: https://www.va.gov/ORO/oro_research_misconduct.asp.

(1) **Allegation.** Allegations of research misconduct that are submitted to VA must be submitted and processed according to the procedures set forth in Appendix A. Based on a review of the allegations, the RIO determines whether the responsible VA medical facility must initiate a research misconduct inquiry.

(2) **Inquiry.** As applicable, an inquiry will be convened by the VA medical facility Director to provide a preliminary assessment of the readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation. For VA-only inquiries, refer to Appendix B. For joint VA/non-VA inquiries led by VA, refer to Appendix C. For joint VA/non-VA inquiries led by the non-VA institution, refer to Appendix D.

(3) **Investigation.** If an investigation is warranted, an Investigation Committee will be convened to review the allegations. The decision to convene an investigation is based on the recommendations of the Inquiry Committee; the VA medical facility Director or ORO can overrule a recommendation to not require an investigation. The Investigation Committee's findings and recommendations for corrective actions, if applicable, are set forth in an Investigation Report. The VA medical facility Director certifies completion of the investigation on behalf of VA and forwards the Investigation Report with additional recommendations, if any, to the ORO-RMO. For VA-only investigations, refer to Appendix B. For joint VA/non-VA investigations led by VA, refer to Appendix C. For joint VA/non-VA investigations led by the non-VA institution, refer to Appendix D.

(4) **Departmental Review.** ORO reviews the case file for procedural sufficiency. If ORO determines that a VA-led proceeding failed to adhere substantially to the requirements of this directive such that the outcome of the case is materially affected, ORO may direct that the same investigation be reopened or a new investigation be opened. Otherwise, the case will be forwarded to the appropriate VISN Director for adjudication.

(5) **Adjudication by the Veterans Integrated Service Network Director.** The VISN Director of the VA medical facility conducting the investigation reviews the final Investigation Report and renders a decision regarding the recommendations for findings and corrective actions in accordance with Appendix E. The VISN Director must transmit this final determination to the ORO-RMO.

(6) **Appeal to the Under Secretary for Health.** The respondent may appeal a finding of research misconduct and proposed corrective actions (including debarment, if applicable, see VHA Directive 1058.04) to the Under Secretary for Health in accordance with Appendix F. The Under Secretary for Health makes a ruling on the respondent's appeal which constitutes VA's final agency action.

b. **References.** For purposes of this directive, the following terms are to be construed as specified.

(1) All references to “day(s)” in this directive mean calendar day(s), unless otherwise noted.

(2) Except as noted in paragraph 8.b.(3), a notification, document, or other submission (“submission”) is to be considered “received” when:

(a) Delivered, if physically handed to the recipient;

(b) Delivered, if mailed to the last known street address, or 5 days after the submission is sent if it is undeliverable;

(c) Sent, if sent by facsimile, or 5 days after the submission is sent if the facsimile is undeliverable; or

(d) Delivered, if sent by Email, or 5 days after the submission is sent if the Email is undeliverable.

(3) “Receipt” of a submission by any VA administrative, oversight, legal, or deciding official or office (including but not limited to a RIO and ORO) will mean “actual receipt.”

c. **Administrative Investigations.** VA investigations of research misconduct under this directive constitute Administrative Investigations as described in VA Directive 0700, Administrative Investigations, dated March 25, 2002, and VA Handbook 0700. VA Research Misconduct Investigation Committees are convened as Administrative Investigation Boards (AIBs). The procedural requirements of VA Handbook 0700 must be observed in all VA-led research misconduct investigations except that the provisions of this directive shall take precedence over any contrary provisions of VA Handbook 0700.

d. **Procedural Exceptions.** Rare circumstances in individual cases of alleged research misconduct may dictate variation from requirements in this directive when deemed in the best interests of VA. Any variation from these procedures must be pre-approved by ORO, must be documented in the case record, and must ensure fair treatment of the respondent. ORO or other individuals with oversight responsibilities for the case (e.g., the RIO) must notify the respondent of all significant variations that will apply to the case. ***NOTE:*** *Reasonable requests for a deadline extension that are submitted by the RIO, VA medical facility Director, or VISN Director and granted by ORO are not considered to be a significant variation.*

e. **Requirements of Other Funding Sources.** If the research at issue in the misconduct allegation is funded in whole or in part by non-VA funding source(s) (e.g., the National Institutes of Health), a separate, additional review of the allegation by the non-VA funding source may be conducted and corrective actions imposed, according to the policies and procedures of that non-VA funding source. ***NOTE:*** *VA-affiliated Nonprofit Research and Education Corporations (NPCs) must adhere to the policies and procedures of this directive and any additional local policies of the VA medical facility for which the NPC administers research funds. The local VA medical facility RIO*

will handle research misconduct allegations associated with research administered through the NPC.

f. **Admissions.** If at any point during a research misconduct proceeding the respondent admits to having committed the alleged research misconduct, the following procedures must be followed in order for the admission to be determined to be sufficient to terminate the proceedings.

(1) The admission must be placed in writing and signed by the respondent.

(2) If the admission by itself does not meet all the elements for establishing a research misconduct finding (see paragraph 6), additional evidence will need to be collected through continued proceedings to establish a finding of research misconduct.

(3) If at any point during the research misconduct proceeding, the respondent submits an admission that appears to meet all the elements for establishing a research misconduct finding, the RIO must forward the written admission and relevant evidentiary exhibits to the ORO-RMO for review.

(a) If ORO determines that the admission meets all the elements for establishing a research misconduct finding, then:

1. ORO will forward the written admission and relevant evidentiary exhibits to the VA medical facility Director for review. The VA medical facility Director's certificate of completion will document that the admission can substitute for an Investigation Report and include recommended corrective action(s).

2. The VA medical facility Director forwards the written admission, evidentiary exhibits, and certificate of completion to the ORO-RMO for transmission to the appropriate VISN Director for adjudication of the corrective action(s) in accordance with Appendix E of this directive.

(b) If ORO determines that the admission does not meet all the elements for establishing a research misconduct finding, the RIO will notify the respondent and may either permit an amendment of the admission or direct the research misconduct proceeding to continue.

g. **VA Appointment Status.** A respondent's VA appointment status at the time an allegation is submitted or anytime thereafter must not affect the decision to initiate or complete a research misconduct proceeding if otherwise required under this directive, even if the respondent's VA appointment status is lost due to resignation or termination. If a respondent who no longer holds a VA appointment chooses not to cooperate, the proceedings under this directive must be completed based on a review of all other available testimony and evidence.

h. **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, the RIO, 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.

(1) Only those individuals who are specifically authorized to review a research misconduct allegation are to be provided with nonpublic information in connection with the proceeding. Any person who receives such information as part of a research misconduct proceeding is obligated to keep that information confidential until otherwise made public or as required by law. ***NOTE:*** *In exercising its responsibilities for providing oversight of allegations of research misconduct and coordinating with other Federal agencies, ORO is authorized to disclose information from a research misconduct proceeding to other Federal agencies for such purposes.*

(2) The R&D Committee and its relevant subcommittees may be informed that a research misconduct allegation has been filed with respect to a particular VA research project subject to their oversight, but they are not otherwise authorized to be informed of the details of the research misconduct case unless, and only to the extent that, an interim action subject to the committee's purview is determined by the RIO in consultation with ORO to be necessary per paragraph 8.i.

(3) Records maintained by the VA medical facility in connection with and during the course of a research misconduct proceeding must be protected to the extent permitted by law from public disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 552), the Privacy Act (5 U.S.C. § 552a), and similar statutes, as applicable and are not otherwise required to be disclosed. This includes records produced as a result of a joint proceeding, such as joint Inquiry and Investigation Reports (including those led by a non-VA institution) that are maintained by VA and are subject to information requests under FOIA.

(4) Individual case files must not be listed or retrieved by individual name or any other information that could easily identify the respondent or informant.

(5) Research misconduct case files are considered VA sensitive information; accordingly, they must be stored and transmitted in conformance with all applicable VA information security policies and procedures. See VA Directive 6500, VA Cybersecurity Program, dated January 23, 2019.

(6) The use and disclosure of protected health information (PHI) and other individually identifiable information (III) in any research misconduct proceeding must comply with all applicable privacy statutes, regulations, and VA policies. See VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016. The VA medical facility Privacy Officer and ORO should be consulted for questions regarding use and disclosure of PHI or III.

i. **Interim Actions.** At any time during a research misconduct proceeding, VA may take interim action(s) as necessary.

(1) In addition to any relevant reporting requirements under VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015, the RIO must provide immediate notice of the following exigencies to ORO, and if appropriate after consultation with ORO, to the Office of Research and Development (ORD), non-VA funding sources, and (if required by applicable regulations, policies or institutional agreements) other Government oversight bodies (e.g., VA Inspector General; VHA Medical Inspector; Department of Health and Human Services Office for Human Research Protections) and institutions with joint jurisdiction over the research:

(a) Public health or safety is at risk, including an immediate need to protect human research subjects or animals;

(b) The resources or interests of VA or non-VA funding sources are threatened;

(c) Research activities are 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; or

(g) There are other reasonable indications that the research community or public must be immediately informed of the research misconduct allegations.

(2) If a Governmentwide suspension is recommended, the procedures set forth in VHA Directive 1058.04 must be followed.

(3) If evidence of actual or possible criminal activity is discovered in connection with a research misconduct proceeding, the provisions of 38 C.F.R. 1.200 – 1.205 for reporting criminal matters must be followed.

(4) At the direction of other Government oversight bodies investigating possible criminal activity (including the VA Office of Inspector General) and in consultation with ORO, a research misconduct proceeding initiated under this directive may be suspended.

(a) Under such suspension, the VA medical facility must halt all activities initiated under this directive 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, unless otherwise protected from such disclosure (e.g., a Certificate of Confidentiality).

(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.

(d) Any publicly available report and conclusions from an intervening Government investigation may be included as evidence, if relevant, in a re-activated research misconduct proceeding.

(e) All re-activated research misconduct proceedings must be completed per this directive, regardless of any conclusions or actions taken as a result of an intervening Government investigation, unless ORO determines that completion of the research misconduct proceeding would not be in the best interests of VA.

j. **Corrective Actions.** For all investigations under this directive that result in recommended finding(s) of research misconduct, the Investigation Committee must recommend appropriate corrective actions that are within VA's authority to implement.

(1) The overarching purpose of recommending and implementing corrective actions is to maintain confidence in the research record.

(2) When the Investigation Committee, and subsequently the VA medical facility Director, recommend corrective actions based on recommended findings of research misconduct, and when the VISN Director renders an adjudication of such recommended findings and associated corrective actions, the following criteria, as applicable, must be considered in determining what corrective action(s) are appropriate:

(a) The extent of the research misconduct (amount, duration, scope).

(b) The degree to which the research misconduct was intentional, knowing, or reckless.

(c) The consequences or potential consequences of the research misconduct (e.g., injury to research subjects, skewing of related research results, waste of VA funds, misleading funding reviewers).

(d) The respondent's position and responsibility for the research project.

(e) The cooperation of the respondent during the inquiry and investigation.

(f) The likelihood of rehabilitation.

(g) Any other extenuating or aggravating circumstances.

(3) The following is a non-exhaustive list of corrective actions, one or more of which may be recommended and implemented based on findings of research misconduct, as appropriate (see paragraph 8.j.(2)). The implementation of these actions may require further proceedings as specified in other VA rules, regulations, or policies.

(a) Governmentwide debarment for a stated period (see paragraph 8.k.).

(b) Prohibition from receiving future VA research funds for a stated period.

(c) Prohibition from conducting VA research for a stated period.

(d) Removal from a VA research project, or suspension or termination of an active research award.

(e) Notification by the VA medical facility to the relevant publication outlet(s) of the finding(s) of research misconduct related to the published article(s) or abstract(s), and a request that such be retracted or corrected.

(f) Monitoring or supervision of current and future VA research for a stated period or until defined contingencies are met.

(g) Required validation of data and/or sources (references and contributors) for a stated period or until defined contingencies are met.

(h) Remedial education or mentoring for a stated period or until defined contingencies are met.

(i) Prohibition from serving on VA research review/funding committees for a stated period.

(4) The Investigation Committee may not recommend any adverse action or disciplinary action as defined in VA Directive 5021. Adverse or disciplinary actions based on research misconduct finding(s) may be separately imposed by VA facility personnel in accordance with VA Directive 5021 and other relevant VA policies and procedures; however, determinations as to whether to impose such actions and the implementation of such actions must be distinct from the research misconduct proceeding.

(5) A VA Investigation Committee must not recommend corrective actions for any research impropriety or noncompliance other than research misconduct except to recommend that identified issues be referred to other appropriate VA entities for resolution.

k. **Governmentwide Debarment.** If an Investigation Committee or VA medical facility Director or VISN Director recommends a Governmentwide debarment based on a finding of research misconduct, the debarment recommendation must adhere to the procedural requirements of VHA Directive 1058.04 in addition to those of this directive. Recommended findings of research misconduct documented in an Investigation Report under this directive may constitute a cause of so serious or compelling a nature that it affects the respondent's present responsibility supporting a debarment per 2 C.F.R. 180.800(d).

l. **Publication of Final Findings of Research Misconduct.** For all findings of research misconduct adjudicated by a VISN Director and, if appealed, upheld by the Under Secretary for Health, VA may publish the respondent's name, the respondent's current or former VA position, a detailed summary of the findings, and the corrective actions imposed, in any venue deemed appropriate. Such venues include, but are not

limited to, Government exclusionary lists (if relevant), the *Federal Register*, ORO's Website, other VA publications, and media outlets. VA may also provide the information referenced in this paragraph to the respondent's current employer and academic affiliates, as well as other entities whose notification would be necessary to implement a corrective action (e.g., journal editorial boards). Any and all publications pursuant to this paragraph are not considered appealable "corrective actions" under this directive.
NOTE: *ORO's Website for research misconduct findings can be located at: https://www.va.gov/ORO/Research_Misconduct_Findings.asp.*

9. INFORMANTS, RESPONDENTS, AND WITNESSES

a. **Informant.** Informant is defined in paragraph 3.k.

(1) VA employees have a responsibility to report suspicions of research misconduct if, after a careful consideration of the facts that are readily available to them in the course of their normal duties, they honestly and reasonably believe there is evidence of research misconduct as defined at paragraph 3.u. Individuals other than VA employees who report allegations of research misconduct may be informants.

(2) Informants must not undertake their own investigation of the suspected misconduct prior to filing an allegation per Appendix A or at any time thereafter.

(3) VA employees, former VA employees, and applicants for VA employment who make allegations of research misconduct consistent with the Whistleblower Protection Act of 1989 may seek redress for retaliation as provided under that Act.

(4) An informant who submits a good faith and reasonable allegation of research misconduct in accordance with Appendix A must be given an opportunity to provide testimony during the inquiry and investigation phases and be informed of the final disposition of the case as it relates to the informant's allegation.

(5) Informants do not otherwise have a right to participate in the review or determination of the alleged misconduct case beyond the specific procedures outlined in this paragraph and in Appendix A.

(6) VA employees whose research misconduct allegations are not made in good faith may be subject to disciplinary measures pursuant to existing VA policies outside of this directive.

b. **Respondent.** Respondent is defined in paragraph 3.w.

(1) Respondents must be given timely, written notification of the research misconduct allegations against them.

(2) Respondents must be given reasonable access to sequestered data and research records, if requested of the RIO, for purposes of continuing any research that is not otherwise restricted and for preparing testimony for interviews conducted by the Inquiry or Investigation Committee as part of a research misconduct proceeding. The

RIO, in consultation with the Inquiry or Investigation Committee Chair, will determine what constitutes reasonable methods of access (e.g., providing copies or an opportunity for supervised review of sequestered materials), timing, and frequency.

(3) In order to respond to allegations of research misconduct, respondents must be given the opportunity to be interviewed and present evidence during the inquiry and the investigation, and to provide comments on the Inquiry Report and the draft Investigation Report. The respondent does not have the right to cross examine other witnesses or be present during interviews of such witnesses.

(4) Upon receipt of the draft Investigation Report from the RIO, respondents must be given reasonable access, as determined by the RIO, to sequestered and testimonial (i.e., witness interview transcript) evidence to the extent that such evidence is relied upon to propose findings of research misconduct and corrective actions, if any, for the purpose of preparing comments to the draft report.

(5) Respondents are required to cooperate in good faith with any inquiry or investigation conducted pursuant to this directive. Research misconduct inquiries and investigations proceed, and research misconduct recommendations and determinations are based on all available evidence, regardless of respondents' participation/cooperation.

(6) The destruction of, absence of, or a respondent's failure to provide research records adequately documenting the questioned research does not constitute research misconduct in itself; however, it may be used as evidence to support a finding of research misconduct as defined at paragraph 3.u where it is established by a preponderance of evidence that:

(a) The respondent intentionally, knowingly, or recklessly destroyed research records required to be retained under applicable records control schedules; or

(b) The respondent failed to produce existing research records for a research misconduct proceeding in a timely manner.

(7) Respondents may obtain, at their own expense, 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 is not permitted to speak for, or on behalf of, the respondent during the inquiry or investigation. ***NOTE:*** *If requested in writing by the respondent, notifications and other case correspondence may be sent to and received by a respondent's legal counsel on behalf of the respondent.*

(8) 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 5 U.S.C. § 2302(b)(8), individuals making such disclosures are covered by the protections of that Act, including protection from retaliation.

(9) Respondents against whom a finding of research misconduct is made under this directive must be afforded an opportunity to appeal that finding and any proposed corrective actions according to Appendix F.

(10) If a non-VA institution has joint jurisdiction over a research misconduct case, or the research in question is subject to the requirements of a non-VA funding source, additional procedures and sanctions of that institution or funding source may also apply.

(11) In cases where there is not a finding of research misconduct, the respondents must be offered reasonable assistance in restoring their reputations as related to the research misconduct allegation(s). For example, the VA medical facility might inform the specific entities to whom the VA medical facility previously disclosed the allegation, if any, of the outcome. Assistance will be provided to the extent deemed appropriate by the VA medical facility Director and within the scope of the VA medical facility leadership's authority. The VA medical facility Director consults with the respondent when determining the type and extent of assistance to be provided to restore the respondent's reputation.

c. **Witness.** Witness is defined in paragraph 3.cc., and includes informants, respondents, and any other person who provides written or oral testimony or documentary or physical evidence relevant to an allegation of research misconduct.

(1) VA employees are required to cooperate in good faith with research misconduct proceedings whether led by a VA medical facility or by a non-VA institution in a joint VA/non-VA proceeding. See VA Handbook 0700 and 38 C.F.R. Sec. 0.735-12(b).

(2) VA employees, former VA employees, and applicants for VA employment who cooperate with a research misconduct proceeding consistent with 5 U.S.C. § 2302(b)(8)-(9), may seek redress for retaliation as provided under that Act.

(3) VA employees who do not cooperate in good faith with research misconduct proceedings are subject to disciplinary measures outside of the requirements of this directive. ***NOTE:*** *The "Summary of Obligations and Rights Related to Witnesses," located in VA Handbook 0700, is applicable in research misconduct proceedings except as otherwise provided in this* directive*.*

(4) Non-VA employees may not be compelled to cooperate with a VA-only research misconduct proceeding. However, non-VA witnesses with relevant information should be encouraged to provide testimony and other relevant evidence in their possession.

(5) Witnesses should provide in person testimony when possible and as determined by the Inquiry and Investigation Committees.

10. JOINT JURISDICTION

a. If it is determined by VA and a non-VA institution that the non-VA institution has joint jurisdiction over a research misconduct allegation (see paragraph 3.p.), the relevant VA medical facility must consult with ORO prior to deciding to conduct or not

conduct a joint inquiry or investigation with the non-VA institution. See Appendices C and D.

(1) 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.

(2) If there are multiple allegations against the same respondent(s) where there is joint jurisdiction over at least one of those allegations, VA and the non-VA institution may conduct a single joint inquiry and investigation. By mutual agreement, the VA and non-VA institutions may in the same proceeding jointly review additional research misconduct allegations against the respondent(s) that would otherwise fall within the jurisdiction of just one of the institutions. In such cases, the institutions may agree that both shall deliberate and vote on recommendations for all research misconduct allegations and any associated corrective actions.

(3) If VA jurisdiction becomes apparent after a non-VA institution has initiated an independent proceeding to assess research misconduct allegation(s), the VA medical facility must notify the ORO-RMO, and a determination will be made regarding how VA will proceed, including possibly: joining in a proceeding initiated by the non-VA institution; initiating its own proceeding; or relying on the findings and recommendations of a completed non-VA proceeding.

(a) If VA conducts its own inquiry or investigation, it may consider as evidence any findings of the non-VA inquiry or investigation of the same research misconduct allegation(s) in addition to any supplemental evidence that VA collects and analyzes in its own proceeding.

(b) VA may join in a non-VA institution investigation that is in progress without conducting an independent inquiry if the non-VA institution has followed 65 FR 76260, Federal Policy on Research Misconduct.

b. 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 the following:

(1) The institution under whose auspices the research in question was conducted.

(2) The institution where the research was physically conducted.

(3) The institution that provided greater financial, staff, and resource support for the research.

(4) The institution maintaining control over the evidence most relevant to the research misconduct allegation.

(5) The institution with legal authority to compel relevant witnesses to cooperate.

(6) The institution with sufficient resources, including potential committee members and administrative staff, to conduct a more timely and thorough inquiry or investigation.

(7) The institution with the most experience in conducting research misconduct investigations.

(8) The extent to which the joint inquiry or investigation would address additional allegations pertinent to only one institution.

c. If a mutual decision is made to conduct a joint inquiry or investigation, the terms of any such joint proceeding must be documented.

(1) The terms of the joint proceeding must be documented in the joint committee appointment or charge letter or a separate document.

(2) The terms that must be specified, include, but are not limited to:

(a) Identification of the participating institutions including specification of the institution that will lead the proceeding.

(b) The purpose, scope, and applicable standard of the proceeding.

(c) The applicable policies and procedures that will be followed.

(d) The name(s) of the respondent(s), as applicable.

(e) A specific description of the allegation(s).

(f) The required time frame for completion of the proceeding.

(g) The requirement for at least one representative from each institution on the joint committee. These representatives must have full deliberating and voting privileges regarding at least the research misconduct allegation(s) within the purview of the institution they are representing.

(h) The scope of each institution's participation. This includes:

1. Whether each institution's representative(s) will also deliberate and vote on research misconduct allegations and the associated corrective actions, if any, that would otherwise not fall within the purview of the institution they are representing.

2. Whether, in a non-VA led joint proceeding, VA's representative(s) will also deliberate and vote on any research impropriety allegations (other than research misconduct) if included in the joint proceeding.

(3) If a non-VA institution is designated as the lead, the VA medical facility RIO must forward a copy of the document(s) specifying the terms of the joint proceeding and the non-VA institution's policies and procedures related to research misconduct to the ORO-RMO.

(a) If the non-VA institution's policies and procedures related to research misconduct are not consistent with 65 FR 76260 or this directive, or are not in VA's interest, VA representatives from the VA medical facility and ORO may enter discussions with the non-VA institution regarding possible revisions of the institution's procedures for the case for VA to participate in the joint proceeding.

(b) Pursuant to the above discussions and any revisions, VA may agree to follow the non-VA institution's procedures even if those procedures differ from the procedures in this directive.

d. If a mutual decision is made to conduct a joint proceeding, the requirements set forth in Appendix C or D, whichever is applicable, must be adhered to.

e. Each institution should exert its own institutional authority, as appropriate, to compel the cooperation of individuals and the production of evidence subject to its authority.

11. TRAINING

a. There are no formal training requirements associated with this directive.

b. Recommended training for VA medical facility RIOs includes training on VA Administrative Investigations, Web-based training on research misconduct, and participation in teleconferences and other forums where ORO personnel present information related to this directive. Contact the ORO-RMO for guidance about appropriate training opportunities.

12. RECORDS MANAGEMENT

a. All records regardless of format (e.g., paper, electronic, electronic systems) created pursuant to this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule (RCS) 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

b. If copies of sequestered research protocols, data, laboratory notebooks and medical records are retained according to RCS 10-1 at the end of a research misconduct case, the originals must be returned to the VA medical facility Research Service if consistent with any corrective actions imposed and as determined by the RIO in consultation with the ACOS for R&D and Office of General Counsel (OGC) as necessary.

c. Upon request, ORO must be given immediate access to any and all records in the possession or under the control of a VA medical facility or VISN office in connection with any current or past research misconduct proceedings.

13. REFERENCES

a. 5 U.S.C. § 2302(b)(8)-(9).

b. 5 U.S.C. § 552a.

c. 38 U.S.C. § 7307.

d. 2 C.F.R. §180.

e. 2 C.F.R. § 180.800(d).

f. 2 C.F.R. Part 801.

g. 38 C.F.R. § 0.735-12(b).

h. 38 C.F.R. § 1.200 – 1.205.

i. 42 C.F.R. Part 93.

j. 48 C.F.R. Chapter 1.

k. 65 FR 76260.

l. VA Directive 0700, Administrative Investigations, dated March 25, 2002.

m. VA Directive 5021, Employee/Management Relations, dated April 15, 2002.

n. VA Directive 6500, VA Cybersecurity Program, dated January 23, 2019.

o. VA Handbook 0700, Administrative Investigations, dated July 31, 2002.

p. VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017.

q. VHA Directive 1200, VHA Research and Development Program, dated May 13, 2016.

r. VHA Directive 1200.05(1), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.

s. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

t. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015.

u. VHA Directive 1058.04, Debarments and Suspensions Based on Impropriety in VA Research, dated November 14, 2019.

v. The policy on plagiarism published by the Office of Research Integrity, United States Department of Health and Human Services located at: https://ori.hhs.gov/ori-policy-plagiarism.

ALLEGATIONS

1. APPLICABILITY

This appendix applies to allegations of research misconduct directly submitted to the Department of Veterans Affairs (VA) by individuals making the allegations. In other instances, such as when allegations are initially submitted to a non-VA entity and then referred to VA, or when allegations are initially submitted to VA by an oversight body or journal, the VA medical facility Research Integrity Officer (RIO) must contact the Office of Research Oversight (ORO) Research Misconduct Officer (RMO) within 1 business day of receipt of the allegation to determine how to proceed.

2. PRE-ALLEGATION CONSULTATION

a. Individuals may, but are not required to, first consult with the RIO of the responsible VA medical facility (see paragraph 3.x in the body of this directive) before deciding whether to submit a formal allegation of research misconduct. A pre-allegation consultation does not constitute a formal allegation of research misconduct.

b. If a consultation is sought, the RIO:

(1) Conveys to the individual any procedural deficiencies identified in the potential allegation;

(2) Explains the procedures for making a formal allegation, the process of investigating and adjudicating research misconduct allegations, and the individual's role, responsibilities and safeguards under these procedures; and

(3) Refers the individual to applicable Veterans Health Administration (VHA) Websites where this directive and related VA medical facility Standard Operating Procedures, if any, are posted. Alternatively, electronic or hard copies of such documents may be provided.

3. FORMAL ALLEGATION

a. If an individual decides to submit a formal allegation of research misconduct, the allegation should be submitted to the RIO of the responsible VA medical facility (see paragraph 3.x in the body of this directive). If submitted to any other VA employee, office, or oversight committee, the allegation must be conveyed to the RIO at the earliest opportunity.

b. The allegation must specify the type(s) of research misconduct (fabrication, falsification, and/or plagiarism) being alleged. If the RIO determines that the allegation does not involve alleged research misconduct, the RIO refers the individual making the allegation to the office or oversight committee responsible for handling such an allegation, as appropriate. To facilitate the assessment of the allegation(s) (see paragraph 4 of this appendix), the RIO requests that the individual submitting a formal allegation provide

specific details about the allegation, to the extent known, including:

(1) A description of the research in question, including protocol title(s), funding source(s), and location(s) where the research was approved and conducted.

(2) The name(s) of the person(s) who conducted the research in question.

(3) The name(s) of the person(s) believed to have committed the alleged research misconduct (i.e., name(s) of the potential respondent(s)) and their relationship to the research project.

(4) Bibliographic information for publications, presentations, or applications where the research in question has appeared or been submitted, if any.

(5) Relevant dates and chronologies.

(6) The current storage location of data from, and records of, the research in question.

(7) Any evidence that suggests the alleged research misconduct was committed intentionally, knowingly, or recklessly.

(8) The basis for the individual's allegation(s), including the individual's relationship to the respondent(s) and the research in question, the individual's access to any underlying evidence, and the potential role of other witnesses.

c. The allegation should be accompanied by all relevant evidence that is within the individual's authorized possession and related to the allegation.

d. If the individual's allegation of research misconduct does not address one or more of the preceding items, the RIO identifies which items have not been addressed and provides the individual an opportunity to supplement the allegation as needed. ***NOTE:*** *A lack of specific details or substantive information may impact the RIO's determination whether a research misconduct inquiry must be initiated in accordance with paragraph 4 below.*

e. Only individuals who submit a written, dated, and signed allegation of research misconduct based on first-hand knowledge of facts pertinent to the allegation are considered informants as defined in paragraph 3.k. in the body of this directive.

f. Oral and anonymous allegations of research misconduct must be acted upon by the RIO as information received from a non-informant source, and all roles and responsibilities otherwise adhering to informants under this directive 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 as described in this appendix.

4. RESEARCH INTEGRITY OFFICER RECEIPT AND PROCESSING OF ALLEGATIONS

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

a. The requirements in paragraphs 4.b and 4.d. of this appendix 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).

b. Within 1 business day of receipt of a formal allegation of research misconduct, the RIO must notify the VA medical facility Director and the ORO-RMO of the allegation. If the Associate Chief of Staff for Research and Development (ACOS/R&D) is not the designated VA medical facility RIO and is not named in the allegation as a respondent, the RIO must also notify the ACOS/R&D within the same time period. The notification to the ORO-RMO must include a copy of the written allegation, if the allegation was submitted in writing.

c. If a non-VA institution has or may have joint jurisdiction over the allegation (see paragraph 3.p in the body of this directive), the RIO must inform the non-VA institution of the allegation upon determination of possible joint jurisdiction (unless the allegation was initially received by the non-VA institution and subsequently forwarded to VA). At the time of notification, the VA RIO must begin discussions with the RIO (or equivalent position) of the non-VA institution about the possibility of conducting joint proceedings (i.e., inquiry and investigation) if each institution independently determines that such proceedings are warranted. See paragraph 10 in the body of this directive.

d. Upon receipt and review of the allegation(s), the RIO will determine whether the threshold for initiating a research misconduct inquiry under this directive has been met or if the allegation falls under another administrative process.

(1) A research misconduct inquiry must be initiated for any formal allegation that, *as alleged*:

(a) Falls within the scope of this directive (see paragraph 7 in the body of this directive);

(b) Meets the definition of research misconduct as set forth in paragraph 6 in the body of this directive;

(c) Does not constitute an accepted practice of the relevant research community;

(d) Does not constitute an honest error or difference of opinion; and

(e) Is not clearly “frivolous” (i.e., without basis in fact or reason).

(2) The RIO documents the determination and justification that an inquiry should or

should not be initiated and forwards that decision to the VA medical facility Director and the ORO-RMO.

(a) If the RIO determines that an inquiry must be initiated, the procedures for conducting an inquiry set forth in Appendix B, C or D as applicable must be followed.

(b) If the RIO determines that an allegation does not satisfy all the requirements of paragraph 4.d.(1) of this appendix, the VA medical facility Director or ORO or both may nonetheless require that an inquiry be initiated according to the procedures set forth in Appendix B, C or D as applicable. Such a decision by the VA medical facility Director or ORO is within their full discretion insofar as that decision is not inconsistent with any other part of this directive. The justification for initiating an inquiry despite a contrary determination by the RIO must be documented in writing by the VA medical facility Director or ORO and retained according to the applicable Records Control Schedule as part of the case file.

(c) If the RIO determines that an allegation does not satisfy the requirements of paragraph 4.d.(1) of this appendix, and both the VA medical facility Director and ORO concur with that determination, a research misconduct inquiry will not be opened for that allegation.

1. The VA medical facility Director must provide written notification to the informant (if applicable) that an inquiry will not be opened. The notification must include the basis for the RIO's determination not to initiate an inquiry.

2. Informants cannot appeal the RIO's determination not to initiate an inquiry.

3. Informants may submit a new allegation of research misconduct if it includes evidence not previously submitted that addresses the basis for the RIO's previous determination not to initiate an inquiry. The same submission requirements and procedures for the RIO's determination apply to any new allegation.

4. The case file must be retained by the VA medical facility according to the applicable Records Control Schedule. See paragraph 12 in the body of this directive.

DEPARTMENT OF VETERANS AFFAIRS-ONLY PROCEEDING

1. APPLICABILITY

This appendix applies only to research misconduct inquiries and investigations for which it has been determined that the Department of Veterans Affairs (VA) has sole institutional jurisdiction over the research misconduct allegation(s), or for which a decision is made that a joint inquiry or investigation will not be convened with non-VA institution(s) that have joint jurisdiction over the allegation(s).

2. INQUIRY

a. **Purpose.** The sole purpose of an inquiry is to provide a preliminary assessment of readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation. An inquiry does not make ultimate determinations or recommendations about whether research misconduct occurred. ***NOTE:*** *An inquiry does not require a full review of all evidence related to the allegation(s) or exhaustive interviews and analyses.*

b. **Standard.** A research misconduct allegation is 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.

(1) The decision factors listed in VA Handbook 0700, Administrative Investigations, dated July 31, 2002, for determining whether to convene an Administrative Investigation Board (AIB) are not to be considered in determining whether to convene a research misconduct investigation under this directive. The standard listed in paragraph 2.b. of this appendix must be used.

(2) An inquiry is not permitted to determine that an allegation lacks sufficient substance to warrant an investigation based solely on a respondent's unsubstantiated claim that the alleged research misconduct was a result of the respondent's honest error.

c. **Procedures.** VA-only inquiries convened pursuant to this appendix must adhere to the following procedures. ***NOTE:*** *In some cases, an inquiry into a research misconduct allegation may be initiated without a named respondent. In such cases, the specific provisions in paragraph 2 of this appendix that are only applicable if a respondent has been identified (e.g., notifications to the respondent, identification of the respondent in other notifications, interviewing of the respondent) do not apply unless and until a respondent is named during the inquiry.*

(1) **Initiation.** The VA medical facility Director must appoint an individual or committee to conduct an inquiry within 30 days after a determination is made that an inquiry is warranted. An inquiry is considered "initiated" at the time the individual or committee is appointed by the VA medical facility Director.

(2) **Required Time Frame.** The research misconduct inquiry must be completed within 60 days from the date of initiation.

(a) All inquiry requirements must be completed within the 60-day time frame including issuance of the Inquiry Report described in paragraph 2.c.(7) of this appendix.

(b) The addition of new allegations and/or respondents during an inquiry does not automatically change the original time frame for completion of the inquiry. However, the VA medical facility Director may request an extension if necessary, according to paragraph 2.c.(2)(c) of this appendix.

(c) If an extension of the time frame is required, the VA medical facility Director must submit a written request for an extension to the Office of Research Oversight (ORO) Research Misconduct Officer (RMO), providing a justification for the extension and a proposed extension period. ORO will grant an extension at its discretion.

(3) **Appointment to Conduct the Inquiry.** The VA medical facility Director must appoint in writing an individual or individuals employed by the VA medical facility to conduct the inquiry according to this paragraph. If a sole individual is appointed to conduct the inquiry, the individual must hold at least a 5/8-paid VA appointment at the responsible VA medical facility and have experience conducting research. This sole individual may be the Research Integrity Officer (RIO).

(a) If a sole individual is appointed to conduct the inquiry, that individual must have appropriate qualifications, as determined by the VA medical facility Director, to conduct the inquiry. These qualifications include:

1. Scientific familiarity with the type of research at issue in the allegation.

2. Professional stature approximately equal to or greater than that of the respondent.

3. No unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

4. Ability to collect and summarize information according to this paragraph in an objective manner within the applicable time frame.

(b) If the VA medical facility Director is unable to identify a suitable individual to conduct the inquiry from within the VA medical facility, a suitable candidate must be appointed from another VA medical facility within the same Veterans Integrated Service Network (VISN), subject to the agreement of the other VA medical facility's Director.

(c) If a committee is appointed by the VA medical facility Director to conduct the inquiry, the chairperson must hold at least a 5/8-paid VA appointment at the responsible VA medical facility and have experience conducting research. The individual must have the appropriate qualifications as indicated in paragraph 2.c.(3)(a) of this appendix. The

qualifications and experience of other individuals appointed to the committee will be determined by the VA medical facility Director; however, these individuals must have no unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

(d) The written appointment letter from the VA medical facility Director must include:

1. The name and position of the individual(s) appointed to conduct the inquiry.

2. The name of the respondent(s).

3. A specific description of the allegation(s) for which a determination was made that an inquiry must be initiated.

4. The research and funding involved (to the extent known).

5. The purpose and applicable standard of the inquiry, as set forth in paragraphs 2.a. and 2.b. of this appendix.

6. The required time frame for completion of the inquiry.

7. The RIO's contact information.

8. If a committee is appointed to conduct the inquiry, the name of the individual who will serve as the chairperson.

(e) If additional allegations of research misconduct arise during the inquiry, the ORO-RMO must be notified by the RIO in accordance with Appendix A and, if required, the allegations added to the scope of the inquiry. When such allegations are added to the inquiry, the VA medical facility Director must amend the appointment letter to include the new allegations.

(f) If additional respondents are named during the inquiry, the VA medical facility Director's appointment letter must be amended to include the new respondents.

(g) The VA medical facility Director's appointment letter, and any amendments thereto, must be copied to the ORO-RMO.

(4) **Sequestration of Evidence.** As soon as possible after a determination is made that an inquiry must be initiated (see paragraph 4 of Appendix A), 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 based on the information available to the RIO at the time of sequestration. The RIO documents the entire process of sequestration and chain of custody. ***NOTE:*** *Refer to VA Handbook 0700 regarding the collection of evidence.*

(a) In most cases, sequestration of evidence must take place prior to or at the time of respondent notification of the opening of an inquiry.

(b) Examples of evidence that often needs to be sequestered include, but are not limited to: laboratory notebooks, study binders, primary data records (e.g., films, print-outs from laboratory equipment), case report forms and data sheets, manuscripts, publications, protocols, grant applications, progress reports, presentations, correspondence including emails, computer hard drives, and information and data stored on network drives.

1. If the evidence to be collected is contained on scientific equipment or information systems shared by other users or required by the respondent to conduct on-going research, the RIO may take custody of copies of the evidence from such equipment rather than sequestering the equipment itself, being careful to preserve or document any relevant evidentiary matters such as date and time stamps, file versions, and change logs.

2. If the RIO determines that not sequestering the equipment might reasonably result in the tampering of primary evidence relevant to the research misconduct proceeding, the RIO has the authority to sequester the equipment under appropriate arrangements.

(5) **Notifications.** The VA medical facility Director must provide separate, written notifications of the opening of an inquiry to the following:

(a) The Respondent. The notification to the respondent must include:

1. The inquiry's purpose and applicable standard.

2. A specific description of the allegation(s) to be reviewed.

3. The research and funding involved (to the extent known).

4. The name(s) and position(s) of the individual(s) appointed to conduct the inquiry.

5. The RIO's contact information.

6. A reference to the VHA Website where this directive is posted (https://www.va.gov/vhapublications/publications.cfm?pub=1) or an electronic or hard copy attachment of this directive.

7. If a committee is appointed to conduct the inquiry, the name of the individual who will serve as the committee's chairperson.

NOTE: *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.*

NOTE: *If additional allegations arise during an inquiry, the respondent(s) must be notified in writing of the additional allegations raised against them.*

(b) The Informant. The notification to the informant must include:

1. The name of the respondent(s) (if any) against whom the informant made the allegation.

2. A specific description of the allegation(s) submitted by the informant for which it was determined that an inquiry must be initiated.

3. The inquiry's purpose and applicable standard.

4. The RIO's contact information.

NOTE: *If more than one informant has submitted allegations that are the subject of the inquiry, a separate notification to each informant must be issued. Only the allegations submitted by the notified informant (and for which it was determined that an inquiry must be initiated) are to be included in the notification to that informant.*

(c) Others. The funding source(s) of the research in question, if any, must be notified of the opening of the inquiry if such notification is required by applicable regulation or policy.

(6) **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 the purpose of the inquiry as set forth at paragraph 2.a of this appendix (i.e., to determine whether a research misconduct allegation has sufficient substance to warrant an investigation).

(a) 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. ***NOTE:*** *Refer to VA Handbook 0700 regarding Procedures for Witness Interviews.*

(b) Legal counsel or other advisors accompanying the respondent during an interview are not permitted to speak for or on behalf of the respondent. If the respondent's legal counsel is present during an interview, a representative from the 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).

(c) All inquiry interviews must be recorded by audio or audio-video. Inquiry interviews may but are not required to be transcribed. The RIO arranges recordings.

(d) Subject matter experts from within or outside VA may be consulted to aid in the review of the evidence; however, only the individual(s) appointed by the VA medical facility Director to conduct the inquiry make the determination about whether the allegation has sufficient substance to warrant an investigation.

(7) **Inquiry Report.** Within the allotted time frame for completing the inquiry specified in paragraph 2.c.(2) of this appendix, the individual or committee appointed to conduct the inquiry must complete a succinct Inquiry Report as follows:

(a) The Inquiry Report must contain the following elements:

1. The name and position of the respondent(s).

2. A detailed summary of the allegation(s) reviewed in the inquiry.

3. The research and funding involved.

4. The basis for why each allegation falls within the scope of this directive (see paragraph 7 in the body of this directive).

5. A recommendation to open or not open an investigation based on the standard set forth in paragraph 2.b of this appendix.

6. A specification of which allegation(s) are recommended to be referred to an investigation, if any.

7. A description of the evidence reviewed.

8. A written analysis of how the evidence supports the recommendation.

(b) The final Inquiry Report must be transmitted to the respondent(s) within the allotted time frame for conducting an inquiry (see paragraph 2.c.(2) of this appendix). The respondent must be afforded no less than 5 business days from receipt of the Inquiry Report to provide any comments in writing to the Inquiry Committee. Any comments submitted must be attached to the Inquiry Report.

d. **VA Disposition of the Inquiry Report**. The following steps must be taken when the Inquiry Report is issued and any comments by the respondent are received and attached:

(1) An electronic copy of the Inquiry Report, attachments, and evidentiary exhibits (as defined in VA Handbook 0700) must be forwarded by the RIO to the ORO-RMO and the VA medical facility Director.

(a) If the Inquiry Report recommends that an investigation be opened for any or all the research misconduct allegation(s), the VA medical facility Director must convene an investigation according to paragraph 3 of this appendix.

(b) If the Inquiry Report recommends that an investigation not be opened for any or all the research misconduct allegation(s), the VA medical facility Director or ORO or both may nonetheless require that an investigation be convened according to paragraph 3 of this appendix. Such a decision by the VA medical facility Director or ORO is within their full discretion insofar as that decision is not inconsistent with any other part of this directive. The justification for convening an investigation despite a contrary recommendation by the inquiry must be documented in writing by the VA medical facility Director or ORO and retained according to the applicable Records Control Schedule as part of the case file.

(c) If the Inquiry Report recommends that an investigation not be opened and both the VA medical facility Director and ORO concur with that recommendation, the VA research misconduct case will be closed.

1. The VA medical facility Director must provide written notification of VA's case closure to the respondent, informant, ORO-RMO, any non-VA institution with joint jurisdiction over the allegation, and all funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

2. The VA medical facility Director must provide reasonable assistance in restoring the respondent's reputation according to paragraphs 5.f.(13) and 9.b.(11) in the body of this directive.

3. The case file must be retained by the VA medical facility according to the applicable Records Control Schedule. See paragraph 12 in the body of this directive.

4. The informant may file a subsequent allegation of research misconduct, but only if the informant submits substantively new allegation(s) or evidence. This will be handled as a new allegation. The procedures for processing such allegations are set forth in Appendix A.

3. INVESTIGATION

a. **Purpose.** The purpose of an investigation convened pursuant to this appendix is to investigate and make recommendations as to whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the elements of a research misconduct finding in paragraph 6 in the body of this directive.

b. **Procedures.** VA-only investigations convened pursuant to this appendix must adhere to the following procedures. ***NOTE:*** *A VA research misconduct investigation constitutes an Administrative Investigation under VA Handbook 0700 and must follow the requirements of that handbook except to the extent that any provision of this paragraph contradicts a provision of VA Handbook 0700 (see paragraph 8.c. in the body of this directive).*

(1) **Convocation.** The VA medical facility Director must convene an investigation of all research misconduct allegations forwarded for investigation by issuing a charge letter per paragraph 3.b.(4) of this appendix within 30 days after a determination is made that an investigation is warranted. The investigation is considered initiated on the date that the charge letter is issued.

(2) **Multiple Respondents.** If more than one respondent is named, the VA medical facility Director must decide whether to convene one investigation for all respondents or convene separate investigations for each respondent.

(a) 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 VA medical facility Director may consider convening separate investigations.

(b) In determining whether to convene a single investigation versus multiple investigations for more than one respondent, the VA medical facility Director with assistance of the RIO and ORO must consider which option would:

1. Best preserve the privacy of affected parties;

2. Be the most efficient use of resources; and

3. Most effectively resolve the allegations of research misconduct.

(c) If separate investigations are convened against individual respondents, the procedures in this paragraph 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.

(3) **Required Time Frame.** The research misconduct investigation must be completed within 120 days from the investigation's initiation.

(a) 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 VA medical facility Director. ***NOTE:*** *See paragraphs 3.b.(9)(e) and (f) of this appendix for required time frames to complete drafts of the Investigation Report.*

(b) The addition of new allegations or respondents during an investigation does not automatically change the original time frame for completion of the investigation.

However, the VA medical facility Director may request an extension if necessary according to paragraph 3.b.(3)(c) of this appendix.

(c) If an extension of the time frame is required, the VA medical facility Director must submit a written request for extension to the ORO-RMO, providing a justification for the extension and a proposed extension period. ORO may grant an extension at its discretion.

(4) **Director's Charge Letter for Investigation Committee Appointments.** The VA medical facility Director must issue a charge letter in accordance with VA Handbook 0700 and the following requirements.

(a) The VA medical facility Director must appoint an Investigation Committee of between three to five employees of the VA medical facility who can review, analyze, and form conclusions about relevant evidence according to this paragraph in an objective manner and within the applicable time frame.

1. 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.

2. As determined by the VA medical facility 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, if feasible, 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 (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The VA medical facility Director must designate one member to serve as the Chair of the Investigation Committee. The chairperson must hold at least a 5/8-paid appointment at the VA medical facility, have experience conducting research, and have a professional stature approximately equal to or greater than that of the respondent(s).

4. The RIO may not be appointed as a member of the Investigation Committee, but must provide administrative and management support to and oversight of the committee.

5. Except for the RIO (see paragraph 3.b.(4)(a)4 of this appendix), individuals appointed to conduct the inquiry may also be appointed as members of the Investigation Committee.

6. If the VA medical facility Director is unable to identify enough qualified individuals from within the VA medical facility to comprise the minimum number of three Investigation Committee members, otherwise qualified candidate(s) must be appointed from another VA medical facility within the same VISN, subject to the agreement of the other VA medical facility's Director.

(b) In addition to the requirements specified in VA Handbook 0700, the VA medical facility Director's charge letter must include the following:

1. The names and positions of the members appointed to the Investigation Committee including specification of the Chair.

2. The name of the respondent(s).

3. A specific description of the allegation(s) for which a determination was made that an investigation be convened.

4. The research and funding involved (to the extent known).

5. The purpose of the investigation as set forth in paragraph 3.a. of this appendix and the elements of a research misconduct finding in paragraph 6 in the body of this directive.

6. The required time frame for completion of the investigation.

7. The RIO's contact information.

8. Specification that the investigation must be conducted in accordance with this directive, that the Investigation Report must be in the standard format outlined in VA Handbook 0700, and that the Investigation Committee must make recommendations as to whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.

(c) If additional allegations of research misconduct arise during the investigation, the ORO-RMO must be notified in accordance with Appendix A, and, if required, the allegations added to the scope of the investigation. When such allegations are added to the investigation, the VA medical facility Director must amend the charge letter to include the new allegations. ***NOTE:*** *Allegations may be added to an investigation even if the added allegations were not the subject of the inquiry that led to the investigation.*

(d) If additional respondents are named during the investigation, the VA medical facility Director must amend the charge letter to include the new respondents, or issue separate charge letters per paragraph 3.b.(2)(c) of this appendix. ***NOTE:*** *Individuals may be named as respondents in an investigation even if the individuals were not named as respondents in the inquiry that led to the investigation.*

NOTE: *The research misconduct Investigation Committee may not be charged with investigating issues beyond research misconduct as defined in paragraph 6 in the body of this directive.*

(e) If additional allegation(s) involving new respondent(s) arise during an investigation, with ORO's concurrence, the allegation(s) and respondent(s) can be added to the existing investigation without conducting an inquiry if there is a reasonable nexus between the new and existing allegations.

(f) The VA medical facility Director must provide the charge letter, and any amendments thereto, to the ORO-RMO.

(5) **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 based on the information available to the RIO at the time of sequestration.

(6) **Notification of Investigation.** The VA medical facility Director must provide separate, written notifications of the opening of an investigation to the following:

(a) The Respondent. The notification to the respondent must include:

1. The investigation's purpose and applicable standard.

2. A specific description of the allegation(s) to be reviewed

3. The research and funding involved (to the extent known).

4. The name and position of the members appointed to the Investigation Committee including specification of the Chair.

5. The RIO's contact information.

6. A reference to the VHA Website where this directive is posted (https://www.va.gov/vhapublications/publications.cfm?pub=1) or an electronic or hardcopy attachment of this directive.

7. An opportunity to object to the appointment of any committee member based on a conflict of interest. If objecting, the respondent must submit a written objection to the VA medical facility Director within 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 medical facility Director. If the VA medical facility Director decides to replace a committee member, the VA medical facility Director must amend the charge letter to reflect the change.

NOTE: *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 Informant. The notification to the informant must include:

1. The name of the respondent(s) against whom the informant made the allegation (if any).

2. A specific description of the allegation(s) submitted by the informant for which a determination was made that an investigation be convened.

3. The investigation's purpose and applicable standard.

4. The name and position of the members appointed to the Investigation Committee including specification of the Chair.

5. The RIO's contact information.

NOTE: *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.*

(c) Others. Notification of the opening of the investigation must be provided to the applicable VISN Director and the funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

NOTE: *If and when any additional allegations and/or respondents are later added to the investigation per paragraphs 3.b.(4)(c) and 3.b.(4)(d) of this appendix, the VA medical facility Director must provide notification of such to the relevant respondent(s) and the relevant informant(s) in accordance with this paragraph.*

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

(a) The appointed Chair of the Investigation Committee must provide overall management of the investigation including setting the schedule of committee activities and delegating tasks as needed to accomplish the objectives of the charge letter. The RIO provides administrative and management support to the Chair and the committee.

(b) Meetings of the Investigation Committee must be in person to the extent feasible or be conducted in a manner that allows real time interaction (i.e., video/teleconferencing).

(c) Minutes of Investigation Committee meetings are not required; however, a chronology of the committee's activities must be documented and included in the case record by the RIO.

(d) To the extent feasible, in-person interviews of the informant, respondent, and other witnesses must be conducted with at least a majority of the Investigation Committee physically present (i.e., not participating by video/teleconferencing), including the Chair.

(e) Final recommendations of the Investigation Committee, including split decisions, must reflect that all appointed members of the committee voted.

(f) 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.

(8) **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. ***NOTE:*** *See also Tips for Effective Investigations located as an appendix to VA Handbook 0700.*

(a) The Investigation Committee must conduct a thorough review of all allegations specified in the VA medical facility Director's charge letter. This will include review of the Inquiry Report, its attachments and relevant evidentiary exhibits, and all other evidence relevant to the allegations.

(b) 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 an investigation, the Investigation Committee through the RIO must notify the ORO-RMO in accordance with Appendix A. Unless there is a reasonable suspicion of additional research misconduct, the Investigation Committee need not conduct an exhaustive review of the respondent's entire research portfolio and publications for such a possibility.

(c) All collected evidence must be organized by the RIO in an indexed investigative file as set forth in VA Handbook 0700.

(d) The informant and respondent must be individually interviewed, if available.

(e) Other witnesses who the Investigation Committee determines are likely able to provide relevant documentary or testimonial evidence must be individually interviewed by the committee if available, and according to paragraph 9.c. in the body of this directive. The informant and respondent each may suggest that other specific witnesses be interviewed, but the final decision to interview any witness belongs solely to the committee.

(f) Legal counsel or other advisors accompanying the respondent during an interview are not permitted to 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).

(g) All investigation interviews must be recorded by audio or audio-video and transcribed (the RIO arranges for a stenographer to attend). Transcripts must be provided to the respective interviewees for correction and included in the case record.

(h) 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 final recommendations regarding the allegation(s).

(i) After fully reviewing and analyzing all the relevant evidence and testimony that are reasonably available, the Investigation Committee formulates recommendations for each allegation about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the elements of a research misconduct finding at paragraph 6 in the body of this directive.

(j) Investigation 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.

(k) The Investigation Committee is not permitted to 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 is not permitted to 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 entities for resolution.

(l) Investigation Committee recommendations of corrective actions, if any, must be made in accordance with paragraph 8.j. in the body of this directive.

(9) **Investigation Report.** Within the applicable time frame for completing the investigation, the Investigation Committee must complete an Investigation Report.

(a) The Investigation Report must indicate the name and position of the respondent(s) and for each allegation:

1. A detailed summary of the allegation;

2. The research and funding involved;

3. The basis for why the allegation falls within the scope of this directive (see paragraph 7 in the body of this directive);

4. Recommendations as to whether and to what extent research misconduct has occurred, and who is responsible, based on the elements of a research misconduct finding set forth at paragraph 6 in the body of this directive;

5. The evidence reviewed;

6. How the preponderance of evidence supports a finding of research misconduct, or that the committee determined that there was not a preponderance of evidence to support a finding of research misconduct; and

7. A response to the respondent's affirmative defenses and any other contrary evidence reviewed by the committee.

(b) If the Investigation Committee recommends that one or more findings of research misconduct be made, the committee must also recommend what, if any, corrective actions are appropriate. If no findings of research misconduct are recommended, the Investigation Committee may not propose any corrective actions.

(c) If the Investigation Committee recommends Governmentwide debarment of the respondent, the report must specifically indicate that such a debarment is being recommended in accordance with the procedures of VHA Directive 1058.04.

(d) The Investigation Report must be in standard format in accordance with VA Handbook 0700 and the VA medical facility Director's charge letter. An index (list) identifying the evidentiary exhibits cited in the report must be prepared in accordance with VA Handbook 0700 to be included as part of the report.

(e) A draft of the Investigation Report must be completed and transmitted to the ORO-RMO and OGC for review at least 60 days prior to the end of the allotted time frame for completing the investigation. 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.

(f) A draft of the body 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. 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 and testimonial (i.e., witness interview transcript) evidence to the extent that such evidence is relied upon to propose findings of research misconduct and corrective actions, if any, for the purpose of preparing comments to the draft report.

(g) Upon receipt and consideration of any responses to the draft report by the respondent, the Investigation Committee must amend the report as appropriate, finalize the report, and attach the full responses of the respondent, if any, to the final report.

(h) All recommendations that are not reached by consensus must indicate the number of committee members in favor of and the number opposed to the final recommendation. At the Chair's discretion, the final report may include a synopsis of the minority viewpoint.

(i) The final Investigation Report must be signed and dated by all members of the committee.

(j) The RIO must ensure the final Investigation Report and accompanying attachments and exhibits, including comments on the draft report if submitted by the respondent, is transmitted to the VA medical facility Director within the allotted time frame for completing the investigation.

c. **VA Disposition of the Investigation Report.**

(1) **VA Medical Facility Director Certification.** Within 30 days of receiving a research misconduct Investigation Report, the VA medical facility Director must certify completion of the investigation on behalf of VA. This includes the following:

(a) The VA medical facility Director must review the Investigation Report, and respondent comments, if submitted, on the draft Investigation Report.

(b) The VA medical facility Director must indicate a concurrence or non-concurrence for each of the Investigation Report's recommendations for the allegations and corrective actions. The VA medical facility Director may recommend additional corrective actions. A written rationale must be provided for each non-concurrence and additional recommended corrective action.

(c) Procedures for implementing disciplinary or adverse actions are not covered by this directive. If the VA medical facility Director decides to impose disciplinary or adverse actions based on the findings of the joint Investigation Committee, those actions must be imposed in accordance with all policies and procedures applicable to such actions. Therefore, the implementation of such disciplinary or adverse actions cannot be appealed under the procedures of this directive.

(d) For cases with multiple respondents, a separate certificate of completion for each respondent is recommended.

(e) The VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the Investigation Report with attachments and evidentiary exhibits (as defined in VA Handbook 0700).

(2) **Office of Research Oversight Procedural Review.** ORO must review the Investigation Report with attachments and evidentiary exhibits, and the VA medical facility Director's certificate of completion, for procedural conformance with this directive.

(a) ORO does not make any substantive determinations regarding the sufficiency of the evidence used to support any recommended findings of research misconduct or corrective actions based thereon, if evidence is cited to support each recommendation for a finding of research misconduct.

(b) Based on the case record and responses to any further inquiries that it may make, ORO must assess whether the procedural requirements set forth in this directive have been satisfied including, but not limited to: timeliness, objectivity, preservation of safeguards, thoroughness, and competence. ORO's procedural review must also include an assessment of whether there has been an appropriate application of the definition of research misconduct (as defined in paragraph 6 in the body of this directive).

1. If ORO determines that the procedural requirements set forth in this directive have been satisfied or that a failure to adhere to the procedural requirements in this directive did not materially affect the outcome of the case, ORO will transmit the following to the relevant VISN Director for adjudication: ORO's procedural determination, a copy of the Investigation Report with evidentiary exhibits and attachments, and the VA medical facility Director's certificate of completion.

2. If ORO determines that a failure to adhere substantially to the procedures set forth in this directive materially affected the outcome of the case, ORO will either require that the VA medical facility Director reopen the investigation using the same Investigation Committee or that the VA medical facility Director charge a new committee to conduct a *de novo* investigation. Unless otherwise specified, all requirements for conducting a research misconduct investigation set forth in this appendix apply. ***NOTE:*** *If the procedural deficiencies identified by ORO pertain to limited aspects (e.g., one of several allegations) of the investigation, ORO may request that the reopened or de novo investigation focus only on those limited aspects.* ORO must transmit a copy of its procedural determination to the VA medical facility Director. Once the re-opened or *de novo* investigation is completed, the VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the Investigation Report along with attachments and evidentiary exhibits (as defined in VA Handbook 0700). ORO must then conduct a procedural review of the re-opened or *de novo* investigation in accordance with paragraph 3.c.(2)(b) of this appendix.

(c) If a Governmentwide debarment has been recommended by the Investigation Committee or the VA medical facility Director, ORO must also determine whether the recommendation is procedurally sufficient per VHA Directive 1058.04, and if so, forward the debarment recommendation to the VISN Director.

(d) ORO's procedural review of the case will normally be completed within 45 days from receipt of case documents transmitted by the VA medical facility Director, and any additional information or clarifications requested by ORO to complete its review.

JOINT DEPARTMENT OF VETERANS AFFAIRS (VA)/NON-VA PROCEEDING LED BY VA

1. APPLICABILITY

This appendix applies to research misconduct inquiries and investigations for which it has been determined that a VA medical facility and a non-VA institution have joint jurisdiction over the research misconduct allegation(s), a joint inquiry or a joint investigation is convened, and VA leads the joint inquiry or joint investigation.

2. INQUIRY

a. **Purpose.** The sole purpose of an inquiry is to provide a preliminary assessment of readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation. An inquiry does not make ultimate determinations or recommendations about whether research misconduct occurred. ***NOTE:*** *An inquiry does not require a full review of all evidence related to the allegation(s) or exhaustive interviews and analyses.*

b. **Standard.** A research misconduct allegation is 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.

(1) The decision factors listed in VA Handbook 0700, Administrative Investigations, dated July 31, 2002 for determining whether to convene an Administrative Investigation Board (AIB) are not to be considered in determining whether to convene a research misconduct investigation under this directive. The standard listed in paragraph 2.b. of this appendix must be used.

(2) An inquiry is not permitted to determine that an allegation lacks sufficient substance to warrant an investigation based solely on a respondent's unsubstantiated claim that the alleged research misconduct was a result of the respondent's honest error.

c. **Procedures.** Joint VA/non-VA inquiries led by VA and convened pursuant to this appendix must adhere to the following procedures. ***NOTE:*** *In some cases, an inquiry into a research misconduct allegation may be initiated without a named respondent. In such cases, the specific provisions in paragraph 2 of this appendix that are only applicable if a respondent has been identified (e.g., notifications to the respondent, identification of the respondent in other notifications, interviewing of the respondent) do not apply unless and until a respondent is named during the inquiry.*

(1) **Initiation.** The VA medical facility Director must appoint a joint Inquiry Committee to conduct an inquiry within 30 days after a determination is made that VA will lead the joint inquiry. An inquiry is considered "initiated" at the time the committee is appointed by the VA medical facility Director.

(2) **Required Time Frame.** The research misconduct inquiry must be completed within 60 days from the date of initiation.

(a) All inquiry requirements must be completed within the 60-day time frame including issuance of the joint Inquiry Report described in paragraph 2.c.(7) of this appendix.

(b) The addition of new allegations and/or respondents during an inquiry does not automatically change the original time frame for completion of the inquiry. However, the VA medical facility Director may request an extension if necessary, according to paragraph 2.c.(2)(c) of this appendix.

(c) If an extension of the time frame is required, the VA medical facility Director must submit a written request for an extension to the Office of Research Oversight (ORO) Research Misconduct Officer (RMO) providing a justification for the extension and a proposed extension period. ORO will grant an extension at its discretion.

(3) **Appointment of the Joint Inquiry Committee.** The VA medical facility Director must appoint in writing the individuals to conduct the inquiry according to this paragraph.

(a) The Chair must hold at least a 5/8-paid VA appointment at the VA medical facility and have experience conducting research. The individual must have appropriate qualifications, as determined by the VA medical facility Director, to conduct the inquiry. These qualifications include:

1. Scientific familiarity with the type of research at issue in the allegation.

2. Professional stature approximately equal to or greater than that of the respondent

3. No unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

4. Ability to collect and summarize information according to this paragraph in an objective manner within the applicable time frame.

(b) The qualifications and experience of other VA individuals appointed to the committee will be determined by the VA medical facility Director; however, these individuals must have no unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

(c) At least one representative employed by the participating non-VA institution must be appointed to the joint Inquiry Committee to represent the non-VA institution’s interests and perspectives.

1. The non-VA representative(s) are nominated by the non-VA institution with concurrence by the VA medical facility Director. A “non-VA representative” may hold a joint appointment at the VA medical facility.

2. The non-VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The non-VA representative(s) serving on the joint Inquiry Committee have deliberating and voting authorities as agreed upon per paragraph 10.c.(2)(h)1. in the body of this directive.

(d) The written appointment letter from the VA medical facility Director must include:

1. The name and position of the individuals appointed to conduct the inquiry.

2. The name of the respondent(s).

3. A specific description of the allegation(s) for which a determination was made that an inquiry must be initiated.

4. The research and funding involved (to the extent known).

5. The purpose and applicable standard of the inquiry, as set forth in paragraphs 2.a. and 2.b. of this appendix.

6. The required time frame for completion of the inquiry.

7. The contact information for the VA medical facility Research Integrity Officer (RIO).

8. The name of the individual who will serve as the Chair of the joint Inquiry Committee, that a joint inquiry is being convened, the basis for the participating non-VA institution’s joint jurisdiction over the allegation(s), and that VA will lead the joint inquiry under the procedures of this directive.

(e) If additional allegations of research misconduct arise during the inquiry, the ORO-RMO must be notified by the RIO in accordance with Appendix A and, if required, the allegations added to the scope of the inquiry. When such allegations are added to the inquiry, the VA medical facility Director must amend the appointment letter to include the new allegations.

(f) If additional respondents are named during the inquiry, the VA medical facility Director must amend the appointment letter to include the new respondents.

(g) The VA medical facility Director’s appointment letter, and any amendments thereto, must be copied to the ORO-RMO.

(4) **Sequestration of Evidence.** As soon as possible after a determination is made that an inquiry must be initiated (see paragraph 4 of Appendix A), 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 based on the information available to the RIO at the time of sequestration. The RIO documents the entire process of sequestration and chain of custody. ***NOTE:*** *Refer to VA Handbook 0700 regarding the collection of evidence.*

(a) In most cases, sequestration of evidence must take place prior to or at the time of respondent notification of the opening of an inquiry.

(b) Examples of evidence that often needs to be sequestered include, but are not limited to: laboratory notebooks, study binders, primary data records (e.g., films, print-outs from laboratory equipment), case report forms and data sheets, manuscripts, publications, protocols, grant applications, progress reports, presentations, correspondence including emails, computer hard drives, and information and data stored on network drives.

1. If the evidence to be collected is contained on scientific equipment or information systems shared by other users or required by the respondent to conduct on-going research, the RIO may take custody of copies of the evidence from such equipment rather than sequestering the equipment itself, being careful to preserve or document any relevant evidentiary matters such as date and time stamps, file versions, and change logs.

2. If the RIO determines that not sequestering the equipment might reasonably result in the tampering of primary evidence relevant to the research misconduct proceeding, the RIO has the authority to sequester the equipment under appropriate arrangements.

(c) For any relevant evidence within the custody of the participating non-VA institution, the joint Inquiry Committee relies upon the authorities of that institution to sequester the relevant evidence.

(5) **Notifications.** The VA medical facility Director must provide separate, written notifications of the opening of a joint inquiry to the following:

(a) The Respondent. The notification to the respondent must include:

1. The inquiry's purpose and applicable standard.

2. A specific description of the allegation(s) to be reviewed

3. The research and funding involved (to the extent known).

4. The name(s) and position(s) of the individual(s) appointed to conduct the inquiry including all non-VA representatives.

5. The RIO's contact information.

6. A reference to the VHA Website where this directive is posted (https://www.va.gov/vhapublications/publications.cfm?pub=1) or an electronic or hardcopy attachment of this directive.

7. The name of the individual who will serve as the joint Inquiry Committee Chair.

8. That a joint inquiry is being convened, the basis for each participating institution's jurisdiction over the allegation, and that VA will lead the joint inquiry under the procedures of this directive.

NOTE: *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.*

NOTE: *If additional allegations arise during an inquiry, the respondent(s) must be notified in writing of the additional allegations raised against them.*

(b) The Informant. The notification to the informant must include:

1. The name of the respondent(s) (if any) against whom the informant made the allegation.

2. A specific description of the allegation(s) submitted by the informant for which it was determined that an inquiry must be initiated.

3. The inquiry's purpose and applicable standard.

4. The RIO's contact information.

5. That a joint inquiry is being convened, the basis for each participating institution's jurisdiction over the allegation, and that VA will lead the joint inquiry under the procedures of this directive.

NOTE: *If more than one informant has submitted allegations that are the subject of the inquiry, a separate notification to each informant must be issued. Only the allegations submitted by the notified informant (and for which it was determined that an inquiry must be initiated) are to be included in the notification to that informant.*

(c) Others. The funding source(s) of the research in question, if any, must be notified of the opening of the inquiry if such notification is required by applicable regulation or policy.

(6) **Interviews and Review of Evidence.** The joint Inquiry Committee reviews the readily available evidence, including evidence submitted by the informant and respondent, sequestered evidence, and testimonial evidence provided in interviews of the informant and the respondent, only as such evidence relates to the purpose of the

inquiry as set forth at paragraph 2.a. of this appendix (i.e., to determine whether a research misconduct allegation has sufficient substance to warrant an investigation).

(a) 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. ***NOTE:*** *Refer to VA Handbook 0700 regarding Procedures for Witness Interviews.*

(b) Legal counsel or other advisors accompanying the respondent during an interview are not permitted to speak for or on behalf of the respondent. If the respondent's legal counsel is present during an interview, a representative from the 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).

(c) All inquiry interviews must be recorded by audio or audio-video. Inquiry interviews may but are not required to be transcribed. The RIO arranges recordings.

(d) Subject matter experts may be consulted to aid in the review of evidence; however, only the individual(s) appointed to conduct the inquiry may make the determination about whether the allegation has sufficient substance to warrant an investigation.

(7) **Inquiry Report.** Within the allotted time frame for completing the inquiry specified in paragraph 2.c.(2) of this appendix, the joint Inquiry Committee must complete a succinct joint Inquiry Report as follows:

(a) The joint Inquiry Report must contain the following elements:

1. The name and position of the respondent(s).

2. A detailed summary of the allegation(s) reviewed in the inquiry.

3. The research and funding involved.

4. The basis for why each allegation falls within the scope of this directive (see paragraph 7 in the body of this directive).

5. A recommendation to open or not open an investigation based on the standard set forth in paragraph 2.b of this appendix.

6. A specification of which allegation(s) are recommended to be referred to an investigation, if any.

7. A description of the evidence reviewed.

8. A written analysis of how the evidence supports the recommendation.

9. The joint Inquiry Report must also indicate that it represents a joint report of the VA medical facility and the participating non-VA institution, provide the basis for the participating non-VA institution's joint jurisdiction over the allegation, and specify that VA led the joint inquiry under the procedures of this directive.

(b) The final joint Inquiry Report must be transmitted to the respondent(s) within the allotted time frame for conducting an inquiry (see paragraph 2.c.(2) of this appendix). The respondent must be afforded no less than 5 business days from receipt of the joint Inquiry Report to provide any comments in writing to the joint Inquiry Committee. Any comments submitted must be attached to the joint Inquiry Report.

(c) The joint Inquiry Report, including attachments and exhibits if requested and as allowed by all applicable policy and law, and submitted comments, if any, from the respondent must be transmitted to the participating non-VA institution with joint jurisdiction within 5 business days after the deadline for receipt of the respondent's comments.

d. **VA Disposition of the Joint Inquiry Report.** The following steps must be taken when the joint Inquiry Report is issued and any comments by the respondent are received and attached:

(1) An electronic copy of the joint Inquiry Report, attachments, and evidentiary exhibits (as defined in VA Handbook 0700) must be forwarded by the RIO to the ORO-RMO and the VA medical facility Director.

(a) If the joint Inquiry Report recommends that an investigation be opened for any or all of the research misconduct allegation(s), the VA medical facility Director must convene an investigation according to paragraph 3 of this appendix.

(b) If the joint Inquiry Report recommends that an investigation not be opened for any or all of the research misconduct allegation(s), the VA medical facility Director or ORO or both may nonetheless require that an investigation be convened according to paragraph 3 of Appendix B or C as applicable. Such a decision by the VA medical facility Director or ORO is within their full discretion insofar as that decision is not inconsistent with any other part of this directive. The justification for convening an investigation despite a contrary recommendation by the joint Inquiry Committee must be documented in writing and retained according to the applicable Records Control Schedule as part of the case file.

(c) If the non-VA institution determines to convene an investigation for any or all of the research misconduct allegation(s) that fall within VA's purview, despite a joint Inquiry Report recommendation otherwise, the VA medical facility Director or ORO or both may, but are not required to, determine that the VA medical facility will participate in a joint investigation of the allegation(s) with the non-VA institution.

(d) If the joint Inquiry Report recommends that an investigation not be opened and

both the VA medical facility Director and ORO concur with that recommendation, the VA research misconduct case will be closed.

1. The VA medical facility Director must provide written notification of VA's case closure to the respondent, informant, ORO-RMO, any non-VA institution with joint jurisdiction over the allegation, and all funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

2. The VA medical facility Director must provide reasonable assistance in restoring the respondent's reputation according to paragraphs 5.f.(13) and 9.b.(11) in the body of this directive.

3. The case file must be retained by the VA medical facility according to the applicable Records Control Schedule. See paragraph 12 in the body of this directive.

4. The informant may file a subsequent allegation of research misconduct, but only if the informant submits substantively new allegation(s) or evidence. This will be handled as a new allegation. The procedures for processing such allegations are set forth in Appendix A.

3. INVESTIGATION

a. **Purpose.** The purpose of an investigation convened pursuant to this appendix is to investigate and make recommendations as to whether and what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the elements of a research misconduct finding at paragraph 6 in the body of this directive.

b. **Procedures.** Joint VA/non-VA investigations led by VA and convened pursuant to this appendix must adhere to the following procedures. ***NOTE:*** *A VA-led, joint research misconduct investigation constitutes an Administrative Investigation under VA Handbook 0700 and must follow the requirements of that handbook except to the extent that any provision of this paragraph contradicts a provision of VA Handbook 0700 (see paragraph 8.c. in the body of this directive).*

(1) **Convocation.** The VA medical facility Director must convene a joint investigation of all research misconduct allegations forwarded for investigation by issuing a charge letter per paragraph 3.b.(4) of this appendix within 30 days after a determination is made that VA will lead the joint investigation. The investigation is considered "initiated" on the date that the charge letter is issued.

(2) **Multiple Respondents.** If more than one respondent is named, the VA medical facility Director must decide whether to convene one investigation for all respondents or convene separate investigations for each respondent.

(a) 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 VA medical facility Director may consider convening separate investigations.

(b) In determining whether to convene a single investigation versus multiple investigations for more than one respondent, the VA medical facility Director with assistance of the RIO and ORO must consider which option would:

1. Best preserve the privacy of affected parties;

2. Be the most efficient use of resources; and

3. Most effectively resolve the allegations of research misconduct.

(c) If separate investigations are convened against individual respondents, the procedures in this paragraph 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.

(3) **Required Time Frame.** The research misconduct investigation must be completed within 120 days from the investigation's initiation.

(a) 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 joint Investigation Report (or parts thereof); receiving and incorporating their comments as appropriate; and submission of the final joint Investigation Report to the VA medical facility Director. ***NOTE:*** *See paragraphs 3.b.(9)(e) and (f) of this appendix for required time frames to complete drafts of the joint Investigation Report.*

(b) The addition of new allegations or respondents during an investigation does not automatically change the original time frame for completion of the investigation. However, the VA medical facility Director may request an extension if necessary, according to paragraph 3.b.(3)(c) of this appendix.

(c) If an extension of the time frame is required, the VA medical facility Director must submit a written request for extension to the ORO-RMO providing a justification for the extension and a proposed extension period. ORO may grant an extension at its discretion.

(4) **Director's Charge Letter for Joint Investigation Committee Appointment.** The VA medical facility Director must issue a charge letter in accordance with VA Handbook 0700 and the following requirements.

(a) The VA medical facility Director must appoint the members of the joint Investigation Committee who can review, analyze, and form conclusions about relevant evidence according to this paragraph in an objective manner and within the applicable time frame. The joint Investigation Committee must have three to five members, at least one of which represents the non-VA institution (see paragraph 3.b.(4)(b) below).

1. The composition of the joint Investigation Committee should preferably be an odd number so that any disagreements about ultimate recommendations can be resolved by a majority vote.

2. As determined by the VA medical facility Director, the joint Investigation Committee must include at least one individual who has scientific familiarity with the type of research at issue in the allegation(s) and, if feasible, 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 (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The VA medical facility Director must designate one member to serve as the chair of the joint Investigation Committee. The chairperson must hold at least a 5/8-paid appointment at the VA medical facility, have experience conducting research, and have a professional stature approximately equal to or greater than that of the respondent(s).

4. The RIO may not be appointed as a member of the joint Investigation Committee, but must provide administrative and management support to and overisght of the committee.

5. Except for the RIO (see paragraph 3.b.(4)(a)4. of this appendix), individuals appointed to conduct the inquiry may also be appointed as members of the joint Investigation Committee.

(b) At least one representative employed by the participating non-VA institution must be appointed to the joint Investigation Committee to represent the non-VA institution's interests and perspectives.

1. The non-VA representative(s) must be nominated by the non-VA institution with concurrence by the VA medical facility Director. A "non-VA representative" may hold a joint appointment at the VA medical facility.

2. The non-VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The non-VA representative(s) serving on the joint Investigation Committee have deliberating and voting authorities as agreed upon per paragraph 10.c.(2)(h)1. in the

body of this directive.

(c) In addition to the requirements specified in VA Handbook 0700, the VA medical facility Director's charge letter must include the following:

1. The names and positions of the members appointed to the joint Investigation Committee including specification of the Chair.

2. The name of the respondent(s).

3. A specific description of the allegation(s) for which a determination was made that an investigation be convened.

4. The research and funding involved (to the extent known).

5. The purpose of the investigation as set forth in paragraph 3.a. of this appendix and the elements of a research misconduct finding in paragraph 6 in the body of this directive.

6. The required time frame for completion of the investigation.

7. The RIO's contact information.

8. Specification that the investigation must be conducted in accordance with this directive, that the joint Investigation Report must be in the standard format outlined in VA Handbook 0700, and that the joint Investigation Committee must make recommendations as to whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.

9. Indication that a joint investigation is being convened, the basis for each institution's jurisdiction over the allegation(s), the name and position of the non-VA representative(s), and specify that VA will lead the joint investigation under the procedures of this directive.

(d) If additional allegations of research misconduct arise during the investigation, the ORO-RMO must be notified in accordance with Appendix A and, if required, the allegations added to the scope of the investigation. When such allegations are added to the investigation, the VA medical facility Director must amend the charge letter to include the new allegations. ***NOTE:*** *Allegations may be added to an investigation even if the added allegations were not the subject of the inquiry that led to the investigation.*

(e) If additional respondents are named during the investigation, the VA medical facility Director must amend the charge letter to include the new respondents or issue separate charge letters per paragraph 3.b.(2)(c) of this appendix. ***NOTE:*** *Individuals may be named as respondents in an investigation even if the individuals were not named as respondents in the inquiry that led to the investigation.*

NOTE: *The research misconduct Investigation Committee may not be charged with investigating issues beyond research misconduct as defined in paragraph 6 in the body of this directive.*

(f) If additional allegation(s) involving new respondent(s) arise during an investigation, with ORO's concurrence, the allegation(s) and respondent(s) can be added to the existing investigation without conducting an inquiry if there is a reasonable nexus between the new and existing allegations.

(g) The VA medical facility Director must provide the charge letter, and any amendments thereto, to the ORO-RMO.

(5) **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 based on the information available to the RIO at the time of sequestration. For any relevant evidence within the custody of the participating non-VA institution, the joint Investigation Committee relies upon the authorities of that institution to sequester the relevant evidence.

(6) **Notification of Investigation.** The VA medical facility Director must provide separate, written notifications of the opening of the joint investigation to the following:

(a) The Respondent. The notification to the respondent must include:

1. The investigation's purpose and applicable standard.

2. A specific description of the allegation(s) to be reviewed.

3. The research and funding involved (to the extent known).

4. The name and position of the members appointed to the joint Investigation Committee including specification of the Chair.

5. The RIO's contact information.

6. A reference to the VHA Website where this directive is posted (https://www.va.gov/vhapublications/publications.cfm?pub=1) or an electronic or hardcopy attachment of this directive.

7. That a joint investigation is being convened, the basis for each institution's jurisdiction over the allegation(s), the name and position of the non-VA representative(s), and that VA will lead the joint investigation under the procedures of this directive.

8. An opportunity to object to the appointment of any committee member based on a conflict of interest. If objecting, the respondent must submit a written objection to the VA medical facility Director within 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 medical facility Director. If the VA medical facility Director decides to replace a committee member, the VA medical facility Director must amend the charge letter to reflect the change.

NOTE: *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 Informant. The notification to the informant must include:

1. The name of the respondent(s) against whom the informant made the allegation (if any).

2. A specific description of the allegation(s) submitted by the informant for which a determination was made that an investigation be convened.

3. The investigation's purpose and applicable standard.

4. The name and position of the members appointed to the joint Investigation Committee including specification of the Chair.

5. The RIO's contact information.

6. That a joint investigation is being convened, the basis for each institution's jurisdiction over the allegation(s), and that VA will lead the joint investigation under the procedures of this directive.

NOTE: *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.*

(c) Others. Notification of the opening of the investigation must be provided to the applicable Veterans Integrated Service Network (VISN) Director and the funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

NOTE: *If and when any additional allegations and/or respondents are later added to the investigation per paragraphs 3.b.(4)(d) and 3.b.(4)(e) of this appendix, the VA medical facility Director must provide notification of such to the relevant respondent(s) and the relevant informant(s) in accordance with this paragraph.*

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

(a) The appointed Chair of the joint Investigation Committee must provide overall management of the investigation including setting the schedule of committee activities

and delegating tasks as needed to accomplish the objectives of the charge letter. The RIO provides administrative and management support to the Chair and the committee.

(b) Meetings of the joint Investigation Committee must be in person to the extent feasible or be conducted in a manner that allows real time interaction (i.e., videoconferencing or teleconferencing).

(c) Minutes of joint Investigation Committee meetings are not required; however, a chronology of the committee's activities must be documented and included in the case record by the RIO.

(d) To the extent feasible, in-person interviews of the informant, respondent, and other witnesses must be conducted with at least a majority of the joint Investigation Committee physically present (i.e., not participating by video/teleconferencing), including the Chair.

(e) Final recommendations of the joint Investigation Committee, including split decisions, must reflect that all appointed members of the committee voted pursuant to the terms of the joint investigation. See paragraph 10.c.(2)(h)1. in the body of this directive.

(f) All collection, review, and analysis of evidence by joint 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.

(g) The non-VA representative(s) serving on the joint Investigation Committee have deliberating and voting authorities as agreed upon per paragraph 10.c.(2)(h)1. in the body of this directive.

(8) **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. ***NOTE:*** *See also Tips for Effective Investigations located as an appendix to VA Handbook 0700.*

(a) The joint Investigation Committee must conduct a thorough review of all allegations specified in the VA medical facility Director's charge letter. This will include review of the Inquiry Report and its attachments, relevant evidentiary exhibits from the inquiry, and all other evidence relevant to the allegations.

(b) 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 an investigation, the joint Investigation Committee through the RIO must notify the ORO-RMO in accordance with Appendix A. Unless there is a reasonable suspicion of additional research misconduct, the joint Investigation Committee need not conduct an exhaustive review of the respondent's entire research portfolio and publications for such a possibility.

(c) All collected evidence must be organized by the RIO in an indexed investigative file as set forth in VA Handbook 0700.

(d) The informant and respondent must be individually interviewed, if available.

(e) Other witnesses who the joint Investigation Committee determines are likely able to provide relevant documentary or testimonial evidence must be individually interviewed if available, and according to paragraph 9.c. in the body of this directive. The informant and respondent each may suggest that other specific witnesses be interviewed, but the final decision to interview any witness belongs solely to the committee.

(f) Legal counsel or other advisors accompanying the respondent during an interview are not permitted to 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).

(g) All investigation interviews must be recorded by audio or audio-video and transcribed (the RIO arranges for a stenographer to attend). Transcripts must be provided to the respective interviewees for correction and included in the case record.

(h) Subject matter experts selected by the joint Investigation Committee may be consulted to aid in the review of the evidence and provide opinions. However, only the appointed joint Investigation Committee is authorized to make the final recommendations regarding the allegation(s).

(i) After fully reviewing and analyzing all the relevant evidence and testimony that are reasonably available, the joint 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, based on the elements of a research misconduct finding at paragraph 6 in the body of this directive.

(j) Joint Investigation 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.

(k) The joint Investigation Committee is not permitted to 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 is not permitted to 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 entities for resolution.

(l) Joint Investigation Committee recommendations of corrective actions, if any, must be made in accordance with paragraph 8.j. in the body of this directive.

(9) **Joint Investigation Report.** Within the applicable time frame for completing the investigation, the Investigation Committee must complete a joint Investigation Report.

(a) The joint Investigation Report must indicate that it represents a joint report of the VA medical facility and the participating non-VA institution, provide the basis for each institution's jurisdiction over the allegation, and specify that VA led the joint investigation under this directive. The report must indicate the name and position of the respondent(s) and for each allegation:

1. A detailed summary of the allegation;

2. The research and funding involved;

3. The basis for why the allegation falls within the scope of this directive (see paragraph 7 in the body of this directive);

4. Recommendations as to whether and what extent research misconduct has occurred, and who is responsible, based on the elements of a research misconduct finding set forth at paragraph 6 in the body of this directive;

5. The evidence reviewed;

6. How the preponderance of evidence supports a finding of research misconduct, or that the committee determined that there was not a preponderance of evidence to support a finding of research misconduct; and

7. A response to the respondent's affirmative defenses and any other contrary evidence reviewed by the committee.

(b) If the joint Investigation Committee recommends that one or more findings of research misconduct be made, the committee must also recommend what, if any, corrective actions are appropriate. If no findings of research misconduct are recommended, the Investigation Committee must not propose any corrective actions.

(c) If the joint Investigation Committee recommends Governmentwide debarment of the respondent, the report must specifically indicate that such a debarment is being recommended in accordance with the procedures of VHA Directive 1058.04.

(d) The joint Investigation Report must be in standard format in accordance with VA Handbook 0700 and the VA medical facility Director's charge letter. An index (list) identifying the evidentiary exhibits cited in the report must be prepared in accordance with VA Handbook 0700 to be included as part of the report.

(e) A draft of the joint Investigation Report must be completed and transmitted to the ORO-RMO and OGC for review at least 60 days prior to the end of the allotted time

frame for completing the investigation. 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 joint Investigation Committee must revise the draft report, as appropriate, prior to sending it to the respondent.

(f) A draft of the body of the joint 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. 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 and testimonial (i.e., witness interview transcript) evidence to the extent that such evidence is relied upon to propose findings of research misconduct and corrective actions, if any, for the purpose of preparing comments to the draft report.

(g) Upon receipt and consideration of any responses to the draft joint Investigation Report by the respondent, the joint Investigation Committee must amend the report as appropriate, finalize the report, and attach the full responses of the respondent, if any, to the final report.

(h) All recommendations that are not reached by consensus must indicate the number of committee members in favor of and the number opposed to the final recommendation. At the Chair's discretion, the final joint Investigation Report may include a synopsis of the minority viewpoint.

(i) The final joint Investigation Report must be signed and dated by all members of the committee.

(j) The final joint Investigation Report and accompanying attachments and exhibits, including comments on the draft report if submitted by the respondent, must be transmitted to the VA medical facility Director within the allotted time frame for completing the investigation.

(k) The final joint Investigation Report and attachments that accompany the report, including comments on the draft report if submitted by the respondent, must be transmitted to the participating non-VA institution with joint jurisdiction within 5 business days after issuance of the report. If the participating non-VA institution with joint jurisdiction requests copies of evidentiary exhibits cited in the final joint Investigation Report, copies of the exhibits may be provided to the extent permitted by policy and law.

c. **VA Disposition of the Joint Investigation Report.**

(1) **VA Medical Facility Director Certification.** Within 30 days of receiving a research misconduct joint Investigation Report, the VA medical facility Director must certify completion of the investigation on behalf of VA. This includes the following:

(a) The VA medical facility Director must review the joint Investigation Report, and respondent comments, if submitted, on the draft joint Investigation Report.

(b) The VA medical facility Director must indicate a concurrence or non-concurrence for each of the joint Investigation Report's recommendations for the allegations and corrective actions that fall within VA's jurisdiction. The VA medical facility Director may also recommend additional corrective actions. A written rationale must be provided for each non-concurrence and additional recommended corrective action.

(c) Procedures for implementing disciplinary or adverse actions are not covered by this directive. If the VA medical facility Director decides to impose disciplinary or adverse actions based on the findings of the joint Investigation Committee, those actions must be imposed in accordance with all policies and procedures applicable to such actions. Therefore, the implementation of such disciplinary or adverse actions cannot be appealed under the procedures of this directive.

(d) For cases with multiple respondents, a separate certificate of completion for each respondent is recommended.

(e) The VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the joint Investigation Report with attachments and evidentiary exhibits (as defined in VA Handbook 0700).

(2) **Office of Research Oversight Procedural Review.** ORO must review the joint Investigation Report with attachments and evidentiary exhibits, and the VA medical facility Director's certificate of completion, for procedural conformance with this directive.

(a) ORO does not make any substantive determinations regarding the sufficiency of the evidence used to support any recommended findings of research misconduct or corrective actions based thereon, if evidence is cited to support each recommendation for a finding of research misconduct.

(b) Based on the case record and responses to any further inquiries that it may make, ORO must assess whether the procedural requirements set forth in this directive have been satisfied including, but not limited to: timeliness, objectivity, preservation of safeguards, thoroughness, and competence. ORO's procedural review must also include an assessment of whether there has been an appropriate application of the definition of research misconduct (as defined in paragraph 6 in the body of this directive).

1. If ORO determines that the procedural requirements set forth in this directive have been satisfied or that a failure to adhere to the procedural requirements in this directive did not materially affect the outcome of the case, ORO will transmit the following to the relevant VISN Director for adjudication: ORO's procedural determination; a copy of the joint Investigation Report with evidentiary exhibits and attachments; and the VA medical facility Director's certificate of completion.

2. If ORO determines that a failure to adhere substantially to the procedures set forth in this directive materially affected the outcome of the case, ORO will either require

that the VA medical facility Director reopen the investigation using the same Investigation Committee or that the VA medical facility Director charge a new committee to conduct a *de novo* investigation. Unless otherwise specified, all requirements for conducting a research misconduct investigation set forth at Appendix B or C will apply, whichever is applicable. ***NOTE:*** *If the procedural deficiencies identified by ORO pertain to limited aspects (e.g., one of several allegations) of the investigation, ORO may request that the reopened or de novo investigation focus only on those limited aspects.*

ORO must transmit a copy of its procedural determination to the VA medical facility Director. Once the re-opened or *de novo* investigation is completed, the VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the Investigation Report along with attachments and evidentiary exhibits (as defined in VA Handbook 0700). ORO must then conduct a procedural review of the re-opened or *de novo* investigation in accordance with paragraph 3.c.(2)(b) of this appendix.

(c) If a Governmentwide debarment has been recommended by the joint Investigation Committee or the VA medical facility Director, ORO must also determine whether the recommendation is procedurally sufficient per VHA Directive 1058.04, and if so, forward the debarment recommendation to the VISN Director.

(d) ORO's procedural review of the case should normally be completed within 45 days from receipt of case documents transmitted by the VA medical facility Director and any additional information or clarifications requested by ORO to complete its review.

JOINT DEPARTMENT OF VETERANS AFFAIRS (VA)/NON-VA PROCEEDNG LED BY NON-VA INSTITUTION

1. APPLICABILITY

This appendix applies to research misconduct inquiries and investigations for which it has been determined that a VA medical facility and a non-VA institution have joint jurisdiction over the research misconduct allegation(s), a joint inquiry or a joint investigation is convened, and the non-VA institution leads the joint inquiry or joint investigation.

2. INQUIRY

a. **Purpose.** The purpose of a joint inquiry convened pursuant to this appendix is to provide a preliminary assessment of readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation.

b. **Procedures.** Joint VA/non-VA inquiries led by the non-VA institution must adhere to the research misconduct inquiry procedures of the non-VA institution, except that:

(1) 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 (FR) 76260.

(2) 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 VA medical facility Research Integrity Officer (RIO) (see paragraph 10.c. in the body of this directive).

(a) The non-VA institution's policies and procedures related to research misconduct also must be provided to the VA medical facility RIO.

(b) The VA medical facility RIO must forward the foregoing documentation and policies and procedures to the Office of Research Oversight (ORO) Research Misconduct Officer (RMO).

(3) VA, including ORO, and the non-VA institution may agree to modify the non-VA institution's procedures to incorporate specific elements of this directive'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 joint Inquiry Report must summarize all substantive procedural modifications.

(4) At least one representative from the VA medical facility must be appointed by the VA medical facility Director to the joint Inquiry Committee to represent VA's interests and perspectives.

(a) The VA representative(s) must be nominated by the VA medical facility 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 medical facility. VA representatives may hold a joint appointment at the participating non-VA institution.

(b) The VA representative(s), like all other members appointed to the joint Inquiry Committee, must not have any unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

(c) The VA representative(s) serving on the joint Inquiry Committee have deliberating and voting authorities as agreed upon per paragraph 10.c.(2)(h)1. in the body of this directive.

(5) If at any point ORO determines that VA's interests are not being served by continued participation in the joint inquiry, it will terminate VA's participation and require the initiation of a VA-only inquiry.

(6) A copy of the joint Inquiry Report and submitted comments from the respondent, if any, must be transmitted to the Director of the VA medical facility with joint jurisdiction within 5 business days of issuance of the report or 5 business days of the deadline for receipt of the respondent's comments, if any, whichever is later.

c. VA Disposition of the Joint Inquiry Report.

(1) An electronic copy of the joint Inquiry Report, attachments, and evidentiary exhibits (as defined in VA Handbook 0700) must be forwarded by the RIO to the ORO-RMO and the VA medical facility Director.

(a) If the joint Inquiry Report recommends that an investigation be opened for any or all the research misconduct allegation(s), an investigation must be convened according to paragraph 3 of this appendix.

(b) If the joint Inquiry Report recommends that an investigation not be opened for any or all of the research misconduct allegation(s) that fall within VA's purview, the VA medical facility Director or ORO or both may nonetheless require that an investigation be convened for any such research misconduct allegation(s) according to paragraph 3 of Appendix B, C or D as applicable. Such a decision by the VA medical facility Director or ORO is within their full discretion insofar as that decision is not inconsistent with any part of this directive. The justification for convening an investigation despite a contrary recommendation by the inquiry must be documented in writing and retained according to the applicable Records Control Schedule in the case file.

(c) If the non-VA institution determines to convene an investigation for any or all of the research misconduct allegation(s) that fall within VA's purview, despite a joint Inquiry Report recommendation otherwise, the VA medical facility Director or ORO or

both may, but are not required to, determine that the VA medical facility will participate in a joint investigation of the allegation(s) with the non-VA institution.

(d) If the joint Inquiry Report recommends that an investigation not be opened and both the VA medical facility Director and ORO concur with that recommendation, the VA research misconduct case will be closed.

1. The VA medical facility Director must provide written notification of VA's case closure to the respondent, informant, ORO-RMO, the non-VA institution with joint jurisdiction over the allegation, and all funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

2. The VA medical facility Director must provide reasonable assistance in restoring the respondent's reputation as related to the research misconduct allegation(s) that fall within VA's purview according to paragraphs 5.f.(13) and 9.b.(11) in the body of this directive.

3. The case file must be retained by the VA medical facility according to the applicable Records Control Schedule. See paragraph 12 in the body of this directive.

4. The informant may file a subsequent allegation of research misconduct, but only if the informant submits substantively new allegation(s) or evidence. This will be handled as a new allegation. The procedures for processing such allegations are set forth in Appendix A.

3. INVESTIGATION

a. **Purpose.** The purpose of a joint investigation convened pursuant to this appendix is to investigate and make recommendations as to whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the elements of a research misconduct finding per 65 FR 76260.

b. **Procedures.** Joint VA/non-VA investigations led by the non-VA institution must adhere to the research misconduct investigation procedures of the non-VA institution, except that:

(1) 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 FR 76260.

(2) 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 VA medical facility RIO (see paragraph 10.c. in the body of this directive).

(a) The non-VA institution's policies and procedures related to research misconduct also must be provided to the VA medical facility RIO.

(b) The VA medical facility RIO must forward the foregoing documentation and policies and procedures to the ORO-RMO.

(3) VA, including ORO, and the non-VA institution may agree to modify the non-VA institution's procedures to incorporate specific elements of this directive'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 joint Investigation Report must summarize all substantive procedural modifications.

(4) At least one representative from the VA medical facility must be appointed by the VA medical facility Director to the joint Investigation Committee to represent VA's interests and perspectives.

(a) The VA representative(s) must be nominated by the VA medical facility 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 medical facility. VA representatives may hold a joint appointment at the participating non-VA institution.

(b) The VA representative(s), like all other members appointed to the joint Investigation Committee, must not have any unmanageable conflicts of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses.

(c) The VA representative(s) serving on the joint Investigation Committee have deliberating and voting authorities as agreed upon per paragraph 10.c.(2)(h)1. in the body of this directive.

(5) 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.

(6) A copy of the final joint Investigation Report and submitted comments from the respondent, if any, must be transmitted to the Director of the VA medical facility with joint jurisdiction within 5 business days of issuance of the report or 5 business days of the deadline for receipt of the respondent's comments, if any, whichever is later.

c. **VA Disposition of the Joint Investigation Report.**

(1) **VA Medical Facility Director Certification.** Within 30 days of receiving a research misconduct joint Investigation Report, the VA medical facility Director must certify completion of the investigation on behalf of VA. This includes the following:

(a) The VA medical facility Director must review the joint Investigation Report, and respondent comments, if submitted, on the draft joint Investigation Report.

(b) The VA medical facility Director must indicate a concurrence or non-concurrence for each of the draft Investigation Report's recommendations for the allegations and corrective actions that fall within VA's jurisdiction and the scope of this directive (see paragraph 7 in the body of this directive). The VA medical facility Director may also recommend additional corrective actions. A written rationale must be provided for each non-concurrence and additional recommended corrective action.

(c) Procedures for implementing disciplinary or adverse actions are not covered by this directive. If the VA medical facility Director decides to impose disciplinary or adverse actions based on the findings of the joint Investigation Committee, those actions must be imposed in accordance with all policies and procedures applicable to such actions. Therefore, the implementation of such disciplinary or adverse actions cannot be appealed under the procedures of this directive.

(d) For cases with multiple respondents, a separate certificate of completion for each respondent is recommended.

(e) The VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the joint Investigation Report with attachments and evidentiary exhibits (as defined in VA Handbook 0700).

(2) **Office of Research Oversight Procedural Review.** ORO must review the process used to address the research misconduct allegation(s) under VA's jurisdiction for adherence to the basic procedural requirements of 65 FR 76260.

(a) ORO does not make any substantive determinations regarding the sufficiency of the evidence used to support any recommended findings of research misconduct or corrective actions based thereon, if evidence is cited to support each recommendation for a finding of research misconduct.

(b) Based on the case record and responses to any further inquiries that it may make, ORO must assess whether the procedural requirements set forth in 65 FR 76260 have been satisfied including, but not limited to: timeliness, objectivity, preservation of safeguards, thoroughness, and competence. ORO's procedural review must also include an assessment of whether there has been an appropriate application of the definition of research misconduct (as defined in paragraph 6 in the body of this directive).

1. If ORO determines that the procedural requirements set forth in 65 FR 76260 have been satisfied or that a failure to adhere to the procedural requirements did not materially affect the outcome of the case, ORO will transmit the following to the relevant VISN Director for adjudication: ORO's procedural determination; a copy of the joint Investigation Report with evidentiary exhibits and attachments; and the VA medical facility Director's certificate of completion.

2. If ORO determines that a failure to adhere substantially to the procedures set forth in 65 FR 76260 materially affected the outcome of the case, ORO will request that

the investigation be reopened. If the non-VA institution declines to reopen the joint investigation, ORO will either require that the VA medical facility Director open a VA-only investigation using the same VA committee members or that the VA medical facility Director charge a new committee to conduct a *de novo* investigation. Unless otherwise specified, all of the requirements for conducting a research misconduct investigation set forth at Appendix B, C or D, will apply, whichever is applicable. ***NOTE:*** *If the procedural deficiencies identified by ORO pertain to limited aspects (e.g., one of several allegations) of the investigation, ORO may request that the reopened or de novo investigation focus only on those limited aspects.* ORO must transmit a copy of its procedural determination to the VA medical facility Director. Once the re-opened or *de novo* investigation is completed, the VA medical facility Director must transmit to the ORO-RMO the certificate of completion and an electronic copy of the Investigation Report along with attachments and evidentiary exhibits (as defined in VA Handbook 0700). ORO must then conduct a procedural review of the re-opened or *de novo* investigation in accordance with paragraph 3.c.(2)(b) of this appendix.

(c) If a Governmentwide debarment has been recommended by the joint Investigation Committee or the VA medical facility Director, ORO must also determine whether the recommendation is procedurally sufficient per VHA Directive 1058.04, and if so, forward the debarment recommendation to the VISN Director.

(d) ORO's procedural review of the case should normally be completed within 45 days from receipt of case documents transmitted by the VA medical facility Director and any additional information or clarifications requested by ORO to complete its review.

VETERANS INTEGRATED SERVICE NETWORK DIRECTOR ADJUDICATION

1. APPLICABILITY

This appendix applies only to the Department of Veterans Affairs (VA) adjudication of research misconduct allegations. VA adjudicates every research misconduct allegation investigated in accordance with the scope of this directive, 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.

2. PURPOSE

The purpose of a Veterans Integrated Service Network (VISN) Director adjudication under this appendix is to make a VA decision, based on recommendations from the investigation, 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.

3. PROCEDURES

a. **Responsibility.** The requirements assigned to the VISN Director in this appendix may be performed by a person or persons designated by the VISN Director except that the final adjudication as documented in a Decision Memorandum must be rendered by the VISN Director.

(1) The VISN Director may not designate any person who has an unmanageable conflict of interest (see paragraph 3.c. in the body of this directive) with respect to the research in question, the respondent, the informant, or other key witnesses to perform any of the procedures described in this appendix.

(2) If, as determined by the Assistant Under Secretary for Health for Operations, the VISN Director has an unmanageable conflict of interest with respect to the research in question, the respondent, the informant, or other key witnesses in adjudicating a case, another VA official must be appointed by the Assistant Under Secretary for Health for Operations as an alternate adjudicator.

b. **Time Frame.** The adjudication, including issuance of a Decision Memorandum, must be completed within 30 days from the VISN Director's receipt of the Investigation Report. If an extension of the time frame is required, the VISN Director must submit a written request for an extension to the Office of Research Oversight (ORO) Research Misconduct Officer (RMO) providing a justification for the extension and a proposed extension period. ORO will grant an extension at its discretion.

c. **Review of Evidence.** The VISN Director must thoroughly review: the Investigation Report; respondent comments, if submitted; the VA medical facility Director's certificate of completion; and ORO's procedural determination.

(1) Prior to receipt of the case, the VISN Director is not to be consulted or otherwise involved in the inquiry or investigation of the allegation, except to the extent that significant and extraordinary conditions require the immediate attention of the VISN Director's office.

(2) The VISN Director may request additional information from VA medical facility personnel and request the Investigation Committee to provide further clarification or analysis.

(3) The VISN Director may consult with ORO, the Office of General Counsel (OGC), or any other person or office with relevant knowledge or expertise.

d. **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. ***NOTE:*** *For cases with multiple respondents, a separate Decision Memorandum for each respondent is recommended.*

(1) The decision must be consistent with the research misconduct definition and all the elements for establishing a research misconduct finding in paragraph 6 in the body of this directive.

(2) The decision may concur with all, some, or none of the recommended findings and corrective actions. The VISN Director may also recommend additional corrective actions. Any decision contrary to the recommendations of the Investigation Committee and/or VA medical facility Director, or a decision to add corrective actions, must be noted, and specific reasons for that decision must be indicated in the Decision Memorandum.

(3) If the Investigation Committee or VA medical facility Director recommended a Governmentwide debarment, the VISN Director's adjudication must either concur or not concur with the recommendation.

e. **Disposition.** The VISN Director must transmit the final Decision Memorandum to the ORO-RMO and the following steps must be taken except for adjudications containing a debarment recommendation (see Appendix F, paragraph 3):

(1) If the VISN Director's Decision Memorandum makes any findings of research misconduct, ORO must provide written notification to the respondent of all findings and corrective actions set forth in the VISN Director's final Decision Memorandum as well as the respondent's opportunity to appeal under Appendix F. A copy of the body of the final Investigation Report, the VA medical facility Director's certificate of completion of the investigation, and the VISN Director's Decision Memorandum must accompany ORO's notification. ***NOTE:*** *If a respondent would like access to administrative attachments and exhibits referenced in the Investigation Report, the request for such access should be directed to the VA medical facility Research Integrity Officer (RIO).* ORO must provide

written notification of the findings and corrective actions to the VA medical facility Director, with a copy of the VISN Director's Decision Memorandum.

(2) If the respondent does not file an appeal of the research misconduct findings and corrective actions within 30 days of receiving notification from ORO (see Appendix F paragraph 2.a.(1)), the research misconduct case shall be closed and the following steps will be taken:

(a) ORO will provide written notification to the respondent and VA medical facility that because an appeal has not been received in the required time frame, the research misconduct findings and corrective actions are final. ORO will also notify any Federal agency with joint jurisdiction over the allegations if and as appropriate.

(b) The VA medical facility Director will provide written notification of the final outcome to the informant (regarding allegations submitted by that informant), any non-VA institution with joint jurisdiction over the allegation(s) (e.g., academic affiliate), and all funding sources of the research in question if any such notification is required by applicable regulation or policy.

(c) The case file must be retained by the VA medical facility according to the applicable Records Control Schedule (see paragraph 12 in the body of this directive).

(3) If the VISN Director's decision memorandum does not make any findings of research misconduct, the research misconduct case shall be closed, and the following steps will be taken:

(a) ORO must transmit the VISN Director's decision memorandum to the VA medical facility Director and notify any Federal agency with joint jurisdiction over the allegations if and as appropriate.

(b) The VA medical facility Director must provide written notification of the case closure to the respondent, informant, any non-VA institution with joint jurisdiction over the allegation(s) (e.g., academic affiliate), and all funding source(s) of the research in question, if any such notification is required by applicable regulation or policy.

(c) The VA medical facility Director must provide reasonable assistance in restoring the respondent's reputation as related to the research misconduct allegation(s) that fall within VA's purview, according to paragraph 9.b.(11) in the body of this directive.

(d) The case file must be retained by the VA medical facility according to the applicable Records Control Schedule (see paragraph 12 in the body of this directive).

APPEAL AND DEBARMENT PROCEEDINGS

1. APPLICABILITY

This appendix applies only to appeals of research misconduct findings and corrective actions imposed by a Veterans Integrated Service Network (VISN) Director's adjudication and to recommended Governmentwide debarments under this appendix. Only named respondents may appeal findings of research misconduct and corrective actions under this appendix. Neither the informant nor any party other than the respondent has a right to appeal a finding or non-finding of research misconduct.

2. APPEALS OF RESEARCH MISCONDUCT FINDINGS AND CORRECTIVE ACTIONS OTHER THAN GOVERNMENTWIDE DEBARMENT

Appeals of research misconduct findings and corrective actions other than Governmentwide debarment must adhere to the following procedures:

a. **Submission of Appeal.** To preserve the opportunity to appeal under this appendix, the respondent must file a written appeal of the research misconduct finding(s) and/or corrective action(s) within 30 days of receiving the Office of Research Oversight (ORO) notification of research misconduct finding(s).

(1) The respondent's written appeal to the Under Secretary for Health must be submitted to ORO within the 30-day period for delivery to the Under Secretary for Health. The respondent must send the appeal to ORO via certified mail or equivalent (i.e., with a verified method of delivery).

(2) The respondent's submission must include the notice of research misconduct finding(s) from ORO, the final Investigation Report not including attachments, the precise research misconduct finding(s) and/or corrective action(s) that are being appealed, a statement of the grounds for the appeal, and any additional evidence that supports the grounds for appeal.

(3) No in-person hearings are provided for under this paragraph.

b. **Review of Appeal.** The Under Secretary for Health or designee will review all appeals that are timely and complete. If the Under Secretary for Health or designee determines that the appeal is not timely or complete, the respondent will be notified that the appeal will not be heard and the case has been closed with the finding(s) of research misconduct and corrective action(s) standing.

(1) The Under Secretary for Health or designee will review all documents submitted by the respondent by the required deadline (see paragraph 2.a.(1) of this appendix), documents submitted by ORO, and any other relevant information.

(2) The Office of General Counsel (OGC), ORO, and other VA resources may be consulted for advice.

(3) The Under Secretary for Health may request additional information or clarifications from relevant and available sources.

c. **Final Agency Decision.** The Under Secretary for Health must make a final decision on the issues appealed by the respondent.

(1) The Under Secretary for Health will issue a written Final Agency Decision.

(2) 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 based on noncompliance with the procedures set forth in this directive will not be grounds for reversing the finding unless the magnitude and consequence of such noncompliance are determined by the Under Secretary for Health to have materially affected the outcome of the case.*

(3) The Final Agency Decision must be consistent with the elements of a research misconduct finding at paragraph 6 in the body of this directive.

(4) The Under Secretary for Health's final written decision should normally be completed within 45 days from receipt of all submissions, information, findings of fact, and requested opinions from ORO, OGC, and others.

d. **Notifications.** Upon the receipt of the Final Agency Decision:

(1) ORO forwards the Final Agency Decision issued by the Under Secretary for Health to the respondent, with copies to the VISN Director, and the VA medical facility Director. ORO also notifies any Federal agency with joint jurisdiction over the allegations if and as appropriate.

(2) The VA medical facility Director will provide written notification of the case closure to the informant, any non-VA institution with joint jurisdiction over the allegation(s) (e.g., academic affiliate), and all funding source(s) of the research in question, if any, if such notification is required by applicable regulation or policy.

e. **For Decisions to Reverse Findings.** If the Under Secretary for Health reverses any findings of research misconduct, the VA medical facility Director must provide reasonable assistance if and as warranted in restoring the respondent's reputation as related to the research misconduct allegation(s) that are reversed according to paragraphs 5.f.(13) and 9.b.(11) in the body of this directive.

f. **For Decisions to Uphold Findings.** If the Under Secretary for Health upholds any finding(s) of research misconduct and corrective actions, these corrective actions must be implemented.

3. GOVERNMENTWIDE DEBARMENT RECOMMENDATIONS

a. If the VISN Director's adjudication includes a recommended Governmentwide debarment as a corrective action under Appendix E (see Appendix E paragraph 3.d.(3)), ORO forwards the VISN Director's recommendation, along with the supporting documentation, to the Under Secretary for Health to decide whether to a propose debarment. The procedures for issuing and contesting a proposed debarment are set forth at VHA Directive 1058.04.

(1) If the Under Secretary for Health does not propose a debarment, ORO must provide, per paragraph 3.e.(1) of Appendix E, written notification to the respondent of the research misconduct finding(s) and any non-debarment corrective action(s), and the opportunity to appeal such finding(s) and/or corrective action(s) under paragraph 2 of this Appendix F.

(2) If the Under Secretary for Health proposes a debarment, ORO must provide, per paragraph 3.e.(1) of Appendix E, notification to the respondent of the research misconduct finding(s) and corrective action(s) and the opportunity to appeal such finding(s) and/or corrective action(s) and/or to contest the proposed debarment as set forth in VHA Directive 1058.04.

b. If a Governmentwide debarment has been proposed, a single administrative proceeding shall be convened if the respondent both contests the proposed debarment and appeals the research misconduct findings and/or other corrective actions. The procedures set forth in VHA Directive 1058.04 and paragraph 2 of this Appendix F shall be used except that any discrepancy between the two policies will be resolved in favor of VHA Directive 1058.04.