RESEARCH MISCONDUCT

1. PURPOSE: This Veterans Health Administration (VHA) Handbook establishes the procedures and other requirements for handling allegations of research misconduct involving Department of Veterans Affairs (VA) employees and/or VA research.

2. SUMMARY OF CHANGES: While retaining the fundamental, existing structure for investigating, adjudicating, and appealing allegations/findings of research misconduct, this revised VHA Handbook refines a number of procedures and outlines new responsibilities in an effort to improve and streamline the process. Based on its long-term experience in overseeing a diverse range of research misconduct cases, the Office of Research Oversight (ORO) has identified a number of common procedural challenges that are not fully addressed in the previous version of the Handbook. This revision implements more robust and efficient procedures for responding to allegations of research misconduct while maintaining procedural objectivity and transparency.

3. RELATED ISSUES: VHA Directive 1058, VHA Handbook 1058.01, VHA Handbook 1058.04, VHA Handbook 1058.06, and VHA Directive 1200.

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

5. RESCISSIONS: VHA Handbook 1058.02, Research Misconduct, dated November 16, 2012, is rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on or before the last working day of February 2019.

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Under Secretary for Health

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RESEARCH MISCONDUCT

1. PURPOSE: This Veterans Health Administration (VHA) Handbook sets forth procedures for reporting, investigating, and resolving allegations of research misconduct involving Department of Veterans Affairs (VA) employees and/or VA research. VA is committed to conducting all of its research activities with utmost integrity. To that end, VA employees engaged in research are prohibited from committing research misconduct as defined in this Handbook. Allegations of research misconduct must be processed according to the procedures set forth in this Handbook. **AUTHORITY:** Title 38, United States Code, §7307, and 65 Federal Register 76260 (December 6, 2000).

NOTE: *This Handbook 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.*

2. BACKGROUND:

a. VHA's research misconduct policy is based on the Federal Policy on Research Misconduct at 65 Federal Register (FR) 76260 (December 6, 2000). The Federal Policy sets forth the responsibilities of research institutions conducting Federally funded research, including VA facilities conducting VA research. These VA facilities, in conjunction with the Veterans Integrated Service Network (VISN) offices as specified in this Handbook, "bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution."

b. The fundamental objective of the Federal and VA policies on research misconduct is to ensure "the accuracy and reliability of the research record" and 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." See definition of "research record" in paragraph 5s.

3. RESEARCH MISCONDUCT AND EVIDENTIARY STANDARD:

a. **Research Misconduct.** Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. ***NOTE:*** *Requests for funding (e.g., VA Merit Award applications) are considered research proposals and submitting such a request is considered to be one example of proposing research.*

(1) **Fabrication.** Fabrication is making up data or results and recording or reporting them.

(2) **Falsification.** Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

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(3) **Plagiarism.** Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. For purposes of this Handbook, plagiarism does not include authorship, credit, or intellectual property disputes among collaborators on the research study in question (see paragraph 4b(3)).

(4) Research misconduct does not include honest error or differences of opinion.

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

(1) There must be a significant departure from accepted practices of the relevant research community; and

(2) The misconduct must be committed intentionally, knowingly, or recklessly; and

(3) The allegation must be proven by a preponderance of evidence (see paragraph 5o).
NOTE: *A higher burden of proof, such as "by clear and convincing evidence" or "beyond a reasonable doubt," should not be required to establish a finding of research misconduct.*

4. SCOPE:

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

(1) Current or former VA employees (see paragraph 5w) who are alleged to have committed research misconduct in proposing, performing, or reviewing VA research, or in reporting VA research results.

(2) Current or former VA employees (see paragraph 5w) who are alleged to have committed research misconduct in proposing, performing, or reviewing non-VA research, or in reporting non-VA research results, while acting in their capacity as VA employees.

(3) 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.

NOTE: *The procedures and requirements of this Handbook also apply to VA contractors.*

b. **Conduct Not Covered Under this Handbook.** The procedures in this Handbook apply exclusively to allegations of research misconduct as defined in paragraph 3a. The conduct listed in paragraph 4b does not fall within the scope of this Handbook. Such conduct may be prohibited and investigated under other applicable statutes, regulations, and/or policies.

(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 (i.e., the record of data or results that embody the facts resulting from scientific inquiry).

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

(3) Authorship or credit 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, etc.) 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. [Adapted from the policy on plagiarism published by the Office of Research Integrity, United States (U.S.) Department of Health and Human Services.]*

(4) Alleged research misconduct committed by an individual who has never been a VA employee (see paragraph 5w) or VA contractor. Such allegations must be referred to the relevant institution, oversight office, and/or journal editor for investigation.

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

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

(7) Any other conduct or behavior that is not specifically covered under the definition of research misconduct at paragraph 3a. See also paragraph 4c(4).

c. **Allegations Other Than Research Misconduct.** The procedures outlined in this Handbook are not applicable to any allegations that do not fall within the definition of research misconduct at paragraph 3a.

(1) If an informant makes both research misconduct and other allegations, only the research misconduct allegation(s) shall be processed according to this Handbook.

(2) Allegations other than those of research misconduct must be referred to the relevant authorities 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 itself form the basis for a recommended finding of research misconduct; nor will any conclusions related to improprieties

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or noncompliance other than research misconduct be made as part of the proceedings under this Handbook.

(4) For joint VA/non-VA proceedings led by the non-VA institution (see pars. 18 and 22), 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 3a and other noncompliance matters in the same proceeding.

5. DEFINITIONS: The following definitions are intended for use only within this Handbook.

a. **Adjudication.** An adjudication is the agency determination of whether or not research misconduct occurred and what corrective actions are appropriate based on a review of the allegation, case file, and recommendations of an Investigation Committee.

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

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 Handbook, 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 Handbook 5021.

e. **Data.** Data means information collected, obtained, recorded, or processed while conducting or performing research. It does not include administrative or other information that has no bearing on the accuracy of the research represented in the research record.

f. **Debarment.** Debarment is an action taken by the Under Secretary for Health to exclude a person from participating in certain covered transactions, including exclusion from applying for, or receiving approval to conduct, VA research. ***NOTE:*** *Debarment is further discussed in VHA Handbook 1058.04.*

g. **Good Faith and Reasonable Allegation.** A good faith and reasonable allegation of research misconduct is an allegation that the informant honestly believes ("good faith") and is reasonable for a person in the informant's position to make in light of the readily available evidence. A research misconduct allegation is not made in good faith if it is made with reckless disregard for or willful ignorance of facts that would negate the allegation.

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

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i. **Informant.** An informant is the individual who submits an initial written, formal allegation of research misconduct. Witnesses who provide information in support of an informant's initial allegation are not considered informants. However, an individual who submits a substantively different written, formal allegation of research misconduct may be considered an additional informant. *NOTE: Individuals who only submit an allegation orally or anonymously are considered to be non-informant sources, and all roles and responsibilities otherwise adhering to informants under this Handbook will be deemed not applicable to the oral or anonymous conveyor of the allegation unless and until the individual subsequently submits an identified, written allegation. In instances where a governmental or institutional oversight body (e.g., Institutional Review Board (IRB)) rather than an individual identifies possible research misconduct, the governmental or institutional oversight body does not constitute an informant.*

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

k. **Investigation.** An investigation is the formal development of a factual record and the examination of that record leading either to a recommendation for finding(s) of research misconduct or a recommendation for no finding of research misconduct. A research misconduct investigation constitutes an "administrative investigation" under VA Handbook 0700.

l. **Investigation Committee.** An Investigation Committee is the committee that is convened to conduct an investigation (see paragraph 5k) into allegations of research misconduct.

m. **Investigation Report.** An Investigation Report is the written report generated by an Investigation Committee that contains findings of fact, conclusions, and recommended corrective actions. Administrative attachments that accompany the Investigation Report and evidentiary exhibits cited in the Investigation Report are not considered to constitute part of the report itself (see description of attachments and exhibits in VA Handbook 0700).

n. **Joint Procedural Jurisdiction.** A VA and non-VA research institution (e.g., a VA facility's academic affiliate) have joint procedural jurisdiction over a common research misconduct allegation if and only if they both have independent legal authority to receive, review, and make determinations on the allegation, and to impose corrective actions for any findings of research misconduct.

o. **Preponderance of Evidence.** Preponderance of evidence means proof by information that, compared with that opposing it, leads to the conclusion that a particular matter or asserted fact is more probably true than not.

p. **Recklessness.** Committing research misconduct "recklessly" is characterized by a conscious or willful disregard for ensuring the accurate representation of the research record that a member of the relevant research community would reasonably exercise in like circumstances.

q. **Research.** Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Research is the term for all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to: research in economics, education,

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linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals. ***NOTE:*** *Research is further discussed in VHA Handbooks 1058.01 and 1200.01.*

r. **Research Integrity Officer (RIO).** The RIO is the appointed official at each VA facility who is responsible for receiving, and providing local oversight of the handling of, formal allegations of research misconduct. The RIO position is a VA facility level position and is distinct from that of the Office of Research Oversight (ORO) Research Misconduct Officer (RMO), (see paragraph 7a).

s. **Research Record.** The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, case report forms and data sheets, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and written documents and materials submitted by the respondent(s) in the course of a research misconduct proceeding.

t. **Respondent(s).** Respondent(s) are the individual(s) against whom allegation(s) of research misconduct are directed and whose actions are the subject of an inquiry or investigation under this Handbook. See paragraph 12. Potential respondents include, but are not limited to, Principal Investigators (PIs), co-PIs, sub-investigators, key personnel, trainees, students, technicians, and research coordinators.

u. **Results.** Results are the scientific outcome(s) of research (as defined in paragraph 5q).

v. **Retaliation.** Retaliation is taking or threatening to take an adverse action within one's authority against an informant or other witness in response to a good faith and reasonable allegation of research misconduct or good faith cooperation with any proceeding covered by this Handbook. An adverse action may include an intentional failure to take a warranted action.

w. **VA Employee.** VA employees include individuals who hold compensated or "without compensation" (WOC) appointments, Intergovernmental Personnel Act (IPA) Agreement personnel, and Special Government Employees (SGE).

x. **VA Facility.** A VA facility is any entity that is operated by VA, including but not limited to VA hospitals, medical centers, and health care systems.

y. **VA Research.** VA research is research conducted by VA employees while on VA time, using VA resources (e.g., equipment), or on VA property including space leased to or used by VA. The research may be funded by VA, by other sponsors, or be unfunded. ***NOTE:*** *VA research is further discussed in VHA Handbooks 1058.01 and 1200.01.*

z. **Witness.** A witness is any person who provides testimonial and/or documentary evidence as part of the proceedings covered by this Handbook, including but not limited to the informant and respondent. Investigation Committee members, administrative personnel, and compliance oversight staff related to a research misconduct proceeding do not constitute "witnesses," unless specifically acting in the capacity of a witness as defined above.

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6. GENERAL PROCEDURES:

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

(1) All references to "day(s)" in this Handbook mean calendar day(s), unless otherwise noted.

(2) Except as noted in paragraph 6a(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 five (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 e-mail, or 5 days after the submission is sent if the e-mail 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."

b. **Administrative Investigations.** Investigations of research misconduct under this Handbook constitute Administrative Investigations (AIs) as described in general at VA Directive 0700 and accompanying VA Handbook 0700. 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 to the extent that any provision of this VHA Handbook 1058.02 contradicts a provision of VA Handbook 0700. In all VA-led research misconduct investigations, the provisions of this Handbook take precedence over any contrary provision of VA Handbook 0700.

c. **Procedural Exceptions.** Particular circumstances in individual cases of alleged research misconduct may dictate variation from the procedures in this Handbook when deemed in the best interests of VA. Any change from these procedures must be pre-approved by ORO, must be documented in the case record, and must ensure fair treatment of the respondent. The respondent should be notified of any changes deemed significant by ORO. ***NOTE:*** *Reasonable requests for a deadline extension that are submitted by the MCD or Adjudicating Official and granted by ORO are not considered to be significant changes.*

d. **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 (NIH)), the following provisions apply:

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(1) If VA is designated as the lead agency for coordinating the response to the allegation (e.g., a VA facility is designated to lead the inquiry and/or investigation), the procedural requirements of this Handbook must be followed.

(2) If VA is not designated as the lead agency for coordinating the response to the allegation (e.g., a non-VA entity is designated to lead the inquiry and/or investigation), the procedural requirements of the lead non-VA entity acting on behalf of and pursuant to the policies of the funding source will be followed in accordance with paragraphs 18 and 22.

(3) For research misconduct proceedings in which the research is funded by a non-VA funding source, 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.

(4) As needed, ORO 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 procedures in this Handbook need to be modified to enable a coordinated response.

NOTE: *VHA Nonprofit Research and Education Corporations (NPC) must adhere to the policies and procedures of this Handbook and any additional local policies of the VA facility for which the NPC administers research funds. The local VA medical center-appointed RIO will handle research misconduct allegations associated with research administered through the NPC.*

e. **Admissions.** If at any point during a research misconduct proceeding the respondent admits to wrongdoing, such admission by itself is not necessarily grounds for termination of the proceedings.

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

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

(3) If the respondent admits to some but not all of the research misconduct allegations, the remaining allegations must be proven by a preponderance of evidence (see paragraph 5o) to establish a finding of research misconduct for the remaining allegations.

f. **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 Handbook, 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 Handbook must be completed based on a review of all other available testimony and evidence.

g. **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

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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 (see VA Handbook 0700).

(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 (see par. 7), ORO is authorized to disclose information from a research misconduct proceeding to other Federal agencies for such purposes.*

(2) The Research and Development (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, 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 6h.

(3) Records maintained by the VA 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) (Title 5 United States Code (U.S.C.) 552), the Privacy Act (Title 5 U.S.C. 552a), and similar statutes, as applicable.

(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 with individually identifiable information are considered VA sensitive information; accordingly, they must be stored and transmitted in conformance with all applicable VA information security policies and procedures. Copies of file documents may be made on a limited basis for the purpose of review by authorized individuals.

(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 Handbook 1605.1. The facility Privacy Officer and ORO should be consulted for questions regarding use and disclosure of PHI or III.

h. **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, the RIO must provide immediate notice of the following exigencies to ORO, and 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

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and Human Services Office for Human Research Protections) and institutions with joint oversight jurisdiction over the research misconduct allegation:

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

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

(c) Research activities should be suspended;

(d) There is reasonable indication of possible violations of civil or criminal law;

(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding;

(f) There is a reasonable indication that the research misconduct proceeding might be made public prematurely; and/or

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

(2) If a Governmentwide suspension is recommended, the procedures set forth at VHA Handbook 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 Title 38 Code of Federal Regulations (CFR) §§ 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 Handbook may be temporarily suspended.

(a) Under such suspension, the VA facility must halt all activities initiated under this Handbook except that all sequestered evidence must be kept secure.

(b) Any evidence collected for the research misconduct proceeding must be provided to authorized officials upon request.

(c) All applicable time frames for completing the research misconduct proceeding once it is re-activated will be adjusted to account for the period of suspension.

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

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

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i. **Corrective Actions.** For all investigations under this Handbook 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) The Investigation Committee may not recommend any adverse action or disciplinary action as defined in VA Handbook 5021. Such adverse or disciplinary actions imposed under procedures separate from this Handbook may be based on final findings of research misconduct only as allowed by and per the procedures of VA Handbook 5021 and other relevant VA policies and procedures.

(3) The Investigation Committee may 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.

(4) When the Investigation Committee, and subsequently the VA 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 knowing, intentional, or reckless;

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

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

(h) Any other extenuating or aggravating circumstances.

(5) The following is a non-exhaustive list of corrective actions, some or all of which may be recommended and implemented based on findings of research misconduct, as appropriate (see paragraph 6i(4)). The implementation of certain of these actions may require further proceedings as specified in other VA rules, regulations, or policies.

(a) Publication of the final finding(s) of research misconduct (see paragraph 6k);

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(b) Governmentwide debarment for a defined period (see paragraph 6j);

(c) Prohibition from conducting VA research for a defined period;

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

(e) Correction or retraction of published article(s);

(f) Monitoring or supervision of future VA research;

(g) Required validation of data and/or sources (references and contributors);

(h) Remedial education and/or mentoring.

NOTE: *Prohibition from future VA employment is not a corrective action allowed to be recommended or implemented.*

j. **Governmentwide Debarment.** If an Investigation Committee or VA facility Director recommends a Governmentwide debarment based on a finding of research misconduct, the debarment recommendation must adhere to the procedural requirements of VHA Handbook 1058.04 in addition to those of this Handbook. Recommended findings of research misconduct documented in an Investigation Report under this Handbook may constitute a "cause of so serious or compelling a nature that it affects [the respondent's] present responsibility" supporting a debarment per Title 2 CFR §180.800(d).

k. **Publication of Final Findings of Research Misconduct.** For all findings of research misconduct adjudicated by a VISN Director and upheld by the Under Secretary for Health on appeal, if any, 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 Web site, 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). ***NOTE:*** *In those cases where there is a determination that the extent of the research misconduct is significant and/or the possible or actual consequences of the research misconduct are significant, it is considered to be in the interests of both VA and the scientific community to publish final findings of research misconduct.*

l. **Records Retention.** All records related to a research misconduct proceeding must be retained and destroyed by the appropriate facility or office according to VHA Records Control Schedule (RCS) 10-1 §XLVII-1&2. ***NOTE:*** *RCS 10-1 can be found at: http://www.va.gov/vhapublications/rcs10/rcs10-1.pdf.*

(1) 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 may be returned to the VA facility Research Service if consistent with any corrective

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actions imposed and as determined by the RIO in consultation with the Associate Chief of Staff (ACOS) for R&D and/or Office of General Counsel (OGC) as necessary.

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

7. RESPONSIBILITIES OF THE OFFICE OF RESEARCH OVERSIGHT: ORO serves as the primary VHA office for advising the Under Secretary for Health and exercising oversight concerning all matters of research compliance and assurance, including human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, debarment for research impropriety, and other matters that the Under Secretary for Health may assign. ORO is responsible for developing and conducting Research Compliance Officer (RCO) education programs as directed by the Under Secretary for Health.

a. The ORO-RMO is responsible for overseeing ORO's Research Misconduct Oversight Program (RMOP) including overall management of all research misconduct allegations involving VA employees and/or VA research.

b. ORO provides direct review, instruction, and guidance pertaining to VA facilities' receipt and investigation of research misconduct allegations, VISN Directors' adjudications, and all appeals to the Under Secretary for Health.

c. For any open research misconduct case, ORO may schedule in-person or telephonic meetings with the facility RIO, the individual(s) appointed to conduct an inquiry, and/or the Investigation Committee to provide more in-depth instruction and guidance on the procedures contained in this Handbook.

d. If at any point during a research misconduct proceeding ORO determines that an allegation does not fall within the scope of this Handbook or does not meet the definition of research misconduct, ORO will require that the allegation no longer be processed under the provisions of this Handbook and/or the termination of the research misconduct case. As appropriate, the allegation must be referred by ORO or the RIO to relevant VA offices.

e. ORO may provide rulings on procedural matters, not inconsistent with the procedures of this Handbook, at its 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 only a respondent may appeal any such ruling to the Under Secretary for Health as part of an overall appeal of research misconduct findings and/or corrective actions (see paragraph 25).

f. Particular circumstances in individual cases of alleged research misconduct may dictate variation from the procedures in this Handbook when deemed in the best interests of VA (see paragraph 6c). Any change from these procedures must be pre-approved by ORO and ensure fair treatment of the respondent. The respondent should be notified of any such changes deemed significant by ORO.

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g. ORO may provide general guidance to the relevant decision-makers about how to analyze relevant evidence and form conclusions. Unless authorized by the USH, ORO will not determine the merits of a case such as proposing findings of research misconduct, corrective actions based thereon, and decisions regarding research misconduct appeals.

h. ORO will provide ongoing guidance on research misconduct issues of a general nature through ORO's Web site and periodic teleconferences, in-person meetings, or other venues with facility RIOs.

i. ORO may notify and consult with other offices and entities at any time if it has reason to believe that a research misconduct proceeding may involve that office or entity. As needed, ORO 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 procedures in this Handbook need to be modified to enable a coordinated response.

8. RESPONSIBILITIES OF VA FACILITIES WITH ACTIVE RESEARCH PROGRAMS: All VA facilities with active research programs must adhere to this Handbook, to include the following requirements:

a. Research misconduct allegations must be submitted or referred to the responsible VA facility, and that facility must respond to such allegations, including initiating an inquiry and convening an investigation if and as required under this Handbook.

(1) The "responsible VA facility" is the VA facility where both the research in question was approved and the respondent(s) was employed, regardless of whether the research was conducted partially or entirely off-site at another VA or non-VA facility.

(2) For allegations pertaining to unapproved VA research, non-VA research activities engaged in by VA employees in their capacity as VA employees, research approved by multiple VA facilities, research involving multiple respondents employed at various VA facilities, and other scenarios not covered by paragraph 8a(1), a "responsible VA facility" will be designated by ORO in consultation with the Director(s) of the applicable VA facility(ies) involved in the research referenced in the allegations. The ORO-RMO will serve as the liaison for communications between/among the relevant VA facilities.

b. If, as determined by ORO, the responsible VA facility is unable to complete the requirements of this Handbook satisfactorily with respect to a specific allegation of research misconduct, the VISN to which the VA facility belongs must appoint an alternate VA facility within the VISN to assume those responsibilities. In such cases, ORO must be consulted on the specific procedures to be followed.

c. The responsible official(s) of each VA facility with an active research program must:

(1) Ensure that all persons conducting research under the auspices of the VA facility are aware of the prohibition against committing research misconduct, which includes providing appropriate training as determined by each VA facility;

(2) Appoint a Research Integrity Officer (RIO) per paragraph 10a;

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(3) Make diligent efforts within the scope of their authority to protect from retaliation all witnesses who cooperate in good faith with a research misconduct proceeding;

(4) Make diligent efforts within the scope of their authority to protect from retaliation informants who make good faith and reasonable allegations of research misconduct;

(5) Afford reasonable assistance to respondents who are not found guilty of committing research misconduct in restoring their reputations to the extent that the VA facility leadership deems appropriate, and within the scope of the VA facility's authority; and

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

9. RESPONSIBILITIES PERTAINING TO VHA PROGRAM OFFICE EMPLOYEES ENGAGED IN RESEARCH: For allegations of research misconduct related to research performed by a VHA Program Office employee, the roles and responsibilities set forth in VHA Handbook 1058.06, Research Conducted by Employees of VHA Program Offices, will apply.

10. RESPONSIBILITIES OF THE RESEARCH INTEGRITY OFFICER: Each VA facility with an active research program must have a designated RIO to receive research misconduct allegations and oversee research misconduct proceedings.

a. The Director of each VA facility with an active research program must appoint, in writing, an individual, who is employed by that facility, to serve as RIO. The individual must have previous experience conducting research and/or providing research administrative oversight, and sufficient institutional authority to be able to fulfill the required responsibilities (see paragraph 10c).

(1) Additional factors that the facility Director should consider when selecting an individual to serve as the RIO include whether the individual has:

(a) Previous experience serving as a RIO;

(b) Previous experience serving on a research misconduct Investigation Committee;

(c) Previous experience serving on an Administrative Investigation Board (AIB); and

(d) The stature and credentials to facilitate the individual's ability to fulfill the responsibilities of the position.

(2) Examples of staff who may be qualified to serve as RIO include, but are not limited to, individuals serving as the ACOS for R&D, Deputy ACOS for R&D, Administrative Officer (AO) for R&D, or RCO. ***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 5c. See paragraph 10d for addressing such situations.*

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b. Any RIO personnel changes must be reported to the ORO-RMO within 30 days.

c. The RIO is responsible for:

(1) Ensuring that all of the facility's employees who are engaged in research activities in their capacities as VA employees are aware of the policies and procedures in this Handbook;

(2) Overseeing the facility's compliance with the provisions of this Handbook;

(3) Receiving and processing formal allegations of research misconduct per paragraph 14d;

(4) Serving as the primary facility liaison with the ORO-RMO for all research misconduct allegations at the facility;

(5) Serving as the primary facility liaison with the RIO (or equivalent position) of any non-VA institution with joint procedural jurisdiction over a research misconduct allegation; and

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

(a) Providing the facility notifications required by this Handbook;

(b) Ensuring that all facility, inquiry, and Investigation Committee responsibilities are satisfied within the required timelines;

(c) Arranging for all necessary resources to be available for the facility's conduct of research misconduct proceedings according to this Handbook;

(d) Timely and securely sequestering all evidence 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; and

(e) Retaining all records of the research misconduct proceeding according to the relevant records control schedule. See paragraph 6l.

d. If the VA 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 particular research misconduct case, the RIO must not participate in the oversight of that particular case. The facility Director must appoint an acting RIO who meets the requirements of paragraph 10a, to oversee such cases.

e. At a minimum, RIOs must become familiar with the policies and procedures established in this Handbook. Additional applicable training that RIOs may consider availing themselves of includes, as available: training on VA Administrative Investigations; Web-based training on research misconduct; and/or participation in teleconferences and other forums where ORO personnel present information related to this Handbook.

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11. INFORMANTS: ***NOTE:*** *"Informant" is defined in paragraph 5i.*

a. VA employees have a responsibility to report suspicions of research misconduct if, after a careful assessment 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 3a.

b. An informant may, but is not required to, make preliminary inquiries of the individual suspected of research misconduct or of that individual's supervisor. However, informants must not undertake their own protracted investigation of the suspected misconduct outside of the procedures set forth in this Handbook prior to filing an allegation per paragraph 14c or at any time thereafter.

c. 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. See Title 5 U.S.C. §1201 Notes, et seq.

d. An informant who submits a good faith and reasonable allegation of research misconduct in accordance with paragraph 14c must be given an opportunity to provide testimony during the inquiry and investigation phases, to review portions of the Investigation Report that relate to the informant's allegation, and to be informed of the general outcome of the inquiry and investigation as it relates to the informant's allegation.

e. 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.

f. VA employees whose research misconduct allegations are not made in good faith may be subject to disciplinary measures pursuant to existing VA policies outside the procedures of this Handbook.

12. RESPONDENTS: ***NOTE:*** *"Respondent" is defined in paragraph 5t.*

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

b. Respondents must be given reasonable access to sequestered data and research records, if requested, for purposes of continuing any research that is not otherwise restricted and preparing testimony for interviews conducted as part of a research misconduct proceeding. The RIO, in consultation with the Inquiry or Investigation Committee Chair, as applicable, will determine what constitutes reasonable methods of access (e.g., providing copies or an opportunity for supervised review of sequestered materials), timing, and frequency.

c. 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 Memorandum and the draft Investigation Report.

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d. Upon receipt of the draft Investigation Report, respondents must be given reasonable access, as determined by the RIO, to all sequestered evidence supporting the proposed findings of research misconduct and proposed corrective actions, if any, for the purpose of preparing comments to the draft report.

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

f. The destruction of, absence of, or a respondent's failure to provide research records adequately documenting the questioned research may be used as evidence to support a finding of research misconduct where it is established by a preponderance of the evidence that:

(1) the respondent had research records and intentionally, knowingly, or recklessly destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner; and

(2) the respondent's conduct under paragraph 12f(1) constituted a significant departure from accepted practices of the relevant research community.

g. 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 may not speak for, or on behalf of, the respondent during the inquiry or investigation. ***NOTE:*** *If requested by the respondent, notifications may be sent to a respondent's legal counsel in lieu of being sent to the respondent.*

h. Respondents are prohibited from retaliating against informants who make good faith and reasonable allegations of research misconduct, even if such allegations are ultimately not substantiated. To the extent that allegations of research misconduct constitute disclosures under the Whistleblower Protection Act of 1989, individuals making such disclosures are covered by the protections of that Act, including protection from retaliation.

i. Respondents against whom a finding of research misconduct is made under these procedures must be afforded an opportunity to appeal that finding and any proposed corrective actions according to paragraph 25 ("Appeal and Debarment Proceedings").

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

k. Respondents who are not found guilty of committing research misconduct must be offered reasonable assistance in restoring their reputations. For example, the VA facility might publicize the outcome in forums in which the allegation was previously publicized (if any) and/or expunge references to the research misconduct allegation from the respondent's personnel file. Assistance will be provided to the extent deemed appropriate by VA facility leadership and within the scope of the VA facility leadership's authority. VA facility leadership should consult

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with the respondent when determining the type and extent of assistance to be provided to restore the respondent's reputation.

13. WITNESSES: ***NOTE:*** *"Witness" is defined in paragraph 5z, and includes informants, respondents, and any other person who provides written and/or oral testimony and/or documentary evidence relevant to an allegation of research misconduct.*

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

b. VA employees, former VA employees, and applicants for VA employment who cooperate with a research misconduct proceeding consistent with the Whistleblower Protection Act of 1989, may seek redress for retaliation as provided under that Act. See Title 5 U.S.C. §1201 Notes, et seq.

c. VA employees who do not cooperate in good faith with research misconduct proceedings may be subject to disciplinary measures (outside the procedures of this Handbook). ***NOTE:*** *A "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 Handbook.*

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

14. ALLEGATIONS:

a. **Applicability.** This paragraph applies solely to allegations of research misconduct directly submitted to 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 RIO must contact ORO within one (1) business day of receipt of the allegation to determine how to proceed.

b. **Pre-Allegation Consultation.** Individuals may, but are not required to, first consult with the RIO of the responsible VA facility (see paragraph 8a) before deciding whether to submit a formal allegation of research misconduct. A pre-allegation consultation does not constitute a formal allegation of research misconduct. If a consultation is sought, the RIO must:

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

(2) Explain 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) Refer the individual to applicable VHA Web sites where this policy and related facility Standard Operating Procedures (SOP), if any, are posted. Alternatively, electronic or hardcopies of such documents may be provided.

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c. **Formal Allegation.** If an individual decides to submit a formal allegation of research misconduct, the allegation should be submitted to the RIO of the responsible VA facility (see paragraph 8a). If submitted to any other VA employee, office, or oversight committee, the allegation must be conveyed to the RIO at the earliest opportunity.

(1) 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 will refer the individual making the allegation to the office or oversight committee responsible for handling such an allegation, as appropriate.

(2) To facilitate the assessment of the allegation(s) (see paragraph 14e), the RIO should request that the individual submitting a formal allegation provide specific details about the allegation, to the extent known, including:

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

(b) The name(s) of the person(s) who conducted the research in question;

(c) The name(s) of the person(s) believed to have committed the alleged research misconduct (i.e., name(s) of the potential respondent(s));

(d) Bibliographic information for publications, presentations, and/or applications where the research in question has appeared or been submitted, if any;

(e) Relevant dates and chronologies;

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

(g) Any evidence that suggests the alleged research misconduct was committed intentionally, knowingly, or recklessly; and

(h) 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.

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

(4) If the individual's allegation of research misconduct does not address one or more of the preceding items, the RIO should identify which items have not been addressed and provide the individual an opportunity to supplement the allegation as needed. ***NOTE:*** *A lack of specific details or substantive information may impact ORO's determination as to whether a research misconduct inquiry must be initiated in accordance with paragraph 14e.*

(5) Individuals who submit a written, dated, and signed allegation of research misconduct shall be considered informants as defined in paragraph 5i, and afforded the opportunity to provide testimony, review relevant sections of the Investigation Report, and be informed of the

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general outcome of the inquiry and investigation as it relates to the individual's allegation (see paragraph 11d).

(6) 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 Handbook 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 paragraph.

d. **RIO Receipt and Processing of Allegation.** The initial formal allegations of research misconduct received by the RIO will be processed according to the following procedures.

(1) Within one (1) business day of receipt of a formal allegation of research misconduct, the RIO must notify the facility Director and ORO of the allegation. If the ACOS/R&D is not the designated 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. All notifications to ORO must include a copy of the written allegation, if the allegation was submitted in writing.

(2) As soon as possible, but no later than 5 business days after receipt of the allegation, the RIO must submit the following information, to the extent known, to ORO:

(a) The specific details about the allegation(s) (see paragraph 14c(2));

(b) Verification that the allegation falls within the scope of this Handbook (see paragraph 4); and

(c) An indication of whether any other institution has joint procedural jurisdiction over the allegation as defined in paragraph 5n.

(3) The notification requirements detailed in paragraph 14d(2) apply to the initial allegation(s) of research misconduct and any subsequent research misconduct allegation from any source raised at any point in a research misconduct proceeding that substantially differs from the initial allegation(s).

(4) If it has been determined that a non-VA institution has or may have joint procedural jurisdiction over the allegation, the RIO must inform the non-VA institution of the allegation within five (5) business days after initial receipt of the allegation (unless the allegation was initially received by the non-VA institution and subsequently forwarded to VA). At the time of notification, the 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/or investigation) in the event that each institution independently determines that such proceedings are warranted.

e. **ORO Determination about Initiating an Inquiry.** Upon receipt and review of information submitted by a RIO per paragraph 14d(2) or any other source, ORO will determine whether the responsible VA facility must initiate a research misconduct inquiry or instead refer the allegation to other administrative processes as appropriate.

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(1) To aid the determination, ORO may request additional information from the RIO and/or request information directly from any relevant source. ***NOTE:*** *The inability or unwillingness of an informant or non-informant source to provide specific details or substantive information with their allegation may impact ORO's determination as to whether a research misconduct inquiry is to be initiated.*

(2) As determined by ORO, a research misconduct inquiry must be initiated for any allegation that on its face (as alleged):

(a) Falls within the scope of this Handbook (see paragraph 4);

(b) Meets the definition of research misconduct as set forth in paragraph 3a;

(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., has no basis in fact or reason).

(3) ORO's determination should normally be completed within 10 days from receipt of all information necessary to make its determination.

f. **Notification of Inquiry Determination.** When ORO completes its determination that an inquiry should or should not be initiated according to paragraph 14e, ORO must notify the relevant facility Director of its determination.

(1) If ORO determines that an allegation does not satisfy the requirements of paragraph 14e(2), it will notify the facility Director that a research misconduct inquiry will not be opened for that allegation and the basis for ORO's determination.

(a) Within 5 business days of receiving ORO's determination that a research misconduct inquiry will not be initiated, the 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 ORO's determination not to initiate an inquiry.

(b) Informants have no right to appeal ORO's determination not to initiate an inquiry.

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

(d) The case file must be retained by the VA facility according to the applicable records control schedule. See paragraph 6l.

(2) If ORO determines that an inquiry must be initiated, the procedures for conducting an inquiry set forth in paragraphs 16, 17, or 18 must be followed.

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15. JOINT PROCEDURAL JURISDICTION: GENERAL PROCEDURES:

a. A determination about whether any non-VA institutions have joint procedural jurisdiction over a research misconduct allegation should have been made no later than five (5) business days after initial receipt of the allegation. See paragraph 14d(2)(c).

b. If it is determined that any non-VA institution has joint procedural jurisdiction over a research misconduct allegation, the relevant VA facility must consult with ORO prior to making a decision to conduct or not conduct a joint inquiry or investigation with the non-VA institution. It is VA policy that in most cases in which VA and a non-VA institution have joint jurisdiction over a research misconduct allegation, it is in VA's interest to conduct a joint inquiry, and if warranted a joint investigation, with the non-VA institution to maximize procedural uniformity and minimize duplication while recognizing institutional autonomy.

c. If a mutual decision is made to conduct a joint proceeding, the decision about which institution will lead the proceeding should be made based on a consideration of the following:

(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 successfully conducting research misconduct investigations.

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

d. If a mutual decision is made to conduct a joint inquiry or investigation, the institution designated as the lead must document the terms of the joint proceeding and provide documentation of such terms to the RIO of the non-lead institution.

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

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

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(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 names and positions of the members appointed to the joint inquiry and/or Investigation Committee, including specification of the Chair and the institution being represented by each member;

(e) The name(s) of the respondent(s), as applicable;

(f) A specific description of the allegation(s);

(g) The research funding involved, if known;

(h) The required timeframe for completion of the proceeding; and

(i) Limits, if any, of each institution's participation.

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

e. If a mutual decision is made to conduct a joint inquiry, the requirements set forth in either paragraph 17 or 18, whichever is applicable, must be adhered to.

f. If a mutual decision is made to conduct a joint investigation, the requirements set forth in either paragraph 21 or 22, whichever is applicable, must be adhered to.

g. Each joint Inquiry and Investigation Committee must include at least one representative from each institution. These representatives must have full deliberating and voting privileges regarding at least all of the research misconduct allegations within the purview of the institution they are representing.

h. 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.

i. Each joint inquiry and investigation must result in a single set of recommendations; however, a minority opinion may be noted in the corresponding reports from these proceedings.

16. VA-ONLY INQUIRY:

a. **Applicability.** This paragraph applies only to research misconduct inquiries for which it has been determined that VA has sole institutional jurisdiction over the research misconduct allegation, or for which all non-VA institutions with joint procedural jurisdiction have indicated that they do not wish to participate in a joint inquiry with VA. The initiation or completion of an

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independent, non-VA inquiry of the same research misconduct allegation(s) does not negate the requirement to conduct a separate, VA-only inquiry under this paragraph.

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

c. **Standard.** A research misconduct allegation must be deemed to have "sufficient substance" to warrant an investigation if the inquiry determines that the readily available evidence would raise a reasonable suspicion of research misconduct.

(1) The Decision Factors listed in VA Handbook 0700 for determining whether to convene an AIB are not to be considered in determining whether to convene a research misconduct investigation under this Handbook.

(2) An inquiry may not 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 honest error.

(3) A VA-only inquiry may deem a research misconduct allegation to have "sufficient substance" to warrant a VA investigation based on a separate, non-VA research misconduct inquiry's determination regarding the same allegation that an investigation is warranted, provided that:

(a) A copy of the non-VA Inquiry Report is provided to the individual or committee conducting the VA-only inquiry; and

(b) The VA-only inquiry determines that the allegation reviewed by the non-VA inquiry falls within the scope of this Handbook (see paragraph 4a); and

(c) The VA-only inquiry considers any additional evidence (testimonial or otherwise) that is provided by the respondent and informant during the course of the VA inquiry.

d. **Procedures.** VA-only inquiries convened pursuant to this paragraph 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 16 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, etc.) do not apply unless and until a respondent is named during the course of an inquiry.*

(1) **Initiation.** The VA facility Director must appoint an individual or committee to conduct an inquiry within ten (10) business days after receiving notice of ORO's determination that an inquiry is warranted. An inquiry is considered "initiated" at the time the individual or committee is appointed by the Director.

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(2) **Required Time Frame.** The research misconduct inquiry must be completed within 45 days from the date of initiation.

(a) All inquiry requirements must be completed within the 45 day time frame including issuance of the Inquiry Memorandum described in paragraph 16d(7).

(b) The addition of new allegations and/or respondents during the course of an inquiry does not automatically change the original time frame for completion of the inquiry. However, the VA facility Director may request an extension if necessary according to paragraph 16d(2)(c).

(c) If an extension of the time frame is required, the VA facility Director must submit a written request for an extension to the ORO-RMO as early as possible but at least five (5) business days prior to the deadline for completing the inquiry, 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 facility Director must appoint in writing an individual or individuals employed by the facility to conduct the inquiry according to this paragraph.

(a) If a sole individual is appointed to conduct the inquiry, the individual must hold at least a 5/8^{ths} paid VA appointment at the facility and have experience conducting research. The individual must have appropriate qualifications, as determined by the VA facility Director, to conduct the inquiry. These qualifications include: scientific familiarity with the type of research at issue in the allegation; professional stature approximately equal to or greater than that of the respondent; no unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses; and ability to collect and summarize information according to this paragraph in an objective and timely manner. ***NOTE:*** *The facility Director may appoint the RIO to conduct the inquiry provided that the RIO has the appropriate qualifications, as indicated in this paragraph.* If the VA facility Director is unable to identify a suitable individual to conduct the inquiry from within the VA facility, a suitable candidate must be appointed from another VA facility within the same VISN, subject to the agreement of the other VA facility's Director.

(b) If a committee is appointed to conduct the inquiry, the chairperson must hold at least a 5/8^{ths} paid VA appointment at the facility and have experience conducting research. The individual must have the appropriate qualifications as indicated in paragraph 16d(3)(a). The qualifications and experience of other individuals appointed to the committee will be determined by the VA facility Director; however, these individuals must have no unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses. ***NOTE:*** *In the event that a potential conflict of interest between a committee member and a witness is identified during the course of an inquiry, the issue must be reported to the facility Director, who will serve as the arbiter of whether a conflict of interest exists. In the event that the Director determines that a conflict of interest exists, the Director must either implement a mechanism for appropriately managing the conflict of interest (e.g., instructing that the committee member be recused from questioning the individual during interviews) or, in the event that the conflict of interest cannot be managed, removing the member from the committee.*

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(c) The written appointment letter must include: the name and position of the individual(s) appointed to conduct the inquiry; the name of the respondent(s); a specific description of the allegation(s) for which ORO determined the inquiry must be initiated; the research and funding involved; the purpose and applicable standard of the inquiry, as set forth in paragraphs 16b and 16c; the required time frame for completion of the inquiry; and the contact information for the RIO. If a committee is appointed to conduct the inquiry, the letter must specify the name of the individual who will serve as the chairperson.

1. If additional allegations of research misconduct arise during the course of the inquiry, ORO must be notified in accordance with paragraph 14d(3) and, if required, the allegations added to the scope of the inquiry. When such allegations are added to the inquiry, the facility Director's appointment letter must be amended to include the new allegations.

2. If additional respondents are named during the course of the inquiry, the facility Director's appointment letter must be amended to include the new respondents.

(4) **Sequestration of Evidence.** As soon as possible after the RIO receives a formal allegation, the RIO must collect, sequester, and inventory all physical materials that might reasonably serve as evidence in determining the merits of the research misconduct allegation. ***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, etc.); case report forms and data sheets; manuscripts; publications; protocols; grant applications; progress reports; presentations; 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, if appropriate, 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.

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

(a) The respondent. The notification to the respondent must include: the inquiry's purpose and applicable standard; a specific description of the allegation(s) to be reviewed; the research and funding involved (if known); the name(s) and position(s) of the individual(s) appointed to conduct the inquiry; and the RIO's contact information. The notification must either reference an applicable VHA Web site where this Handbook is posted or include an electronic or hardcopy

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attachment of the Handbook. If a committee is appointed to conduct the inquiry, the letter must specify the name of the individual who will serve as the committee's chairperson.

1. 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.

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

(b) The informant. The notification to the informant must include the name of the respondent(s) against whom the informant made the allegation, a specific description of the allegation(s) submitted by the informant for which ORO determined the inquiry must be initiated, the inquiry's purpose and applicable standard, and the RIO's contact information. If more than one informant has submitted allegations that are the subject of the inquiry, separate notifications to each informant must be issued. Only the allegations submitted by the notified informant (and for which ORO determined the inquiry must be initiated) are to be included in the notification to that informant.

(c) Others. The ORO-RMO, the relevant VISN Director, any non-VA institution with joint procedural jurisdiction over the allegation, and any non-VA funding source if such notification is required by applicable regulation or policy.

1. Notification to this group must include the information contained in the inquiry appointment letter (see paragraph 16d(3)(c)), and may be accomplished by copying those offices on the appointment letter. This group must also be copied on any amendments to the appointment letter.

2. The notifications to the non-VA institution with joint procedural jurisdiction and the non-VA funding source, if any, should be to the office(s) responsible for receiving and processing research misconduct allegations.

(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 16b (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 may not speak for or on behalf of the respondent. If the respondent's legal counsel is present during an interview, a representative from OGC should, to the extent possible, either be physically present or participate in a manner that enables real time interaction (e.g., via teleconference).

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(c) All inquiry interviews must be recorded. Inquiry interviews may, but are not required to, be transcribed.

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

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

(a) The Inquiry Memorandum must contain the following elements: the name and position of the respondent(s); a detailed summary of the allegation(s) reviewed in the inquiry; the research and funding involved; the basis for why each allegation falls within the scope of this Handbook (see par. 4); a recommendation to open or not open an investigation based on the standard set forth in paragraph 16c; a specification of which allegation(s) are recommended to be referred to an investigation, if any; a description of the evidence reviewed; and a written analysis of how the evidence supports the recommendation. If a VA-only inquiry deems a research misconduct allegation to have "sufficient substance" to warrant an investigation on the basis that a separate, non-VA inquiry determined that a research misconduct investigation was warranted (see paragraph 16c(3)), the Inquiry Memorandum also must: summarize the basis for the non-VA inquiry's determination; indicate that the VA inquiry concurs with the non-VA inquiry's determination; and have as an attachment a copy of the non-VA institution's Inquiry Report.

(b) The Inquiry Memorandum must be transmitted to the respondent(s) within the allotted time frame for conducting an inquiry (i.e., within 45 calendar days after initiation of the inquiry unless a deadline extension for completing the inquiry has been granted). The respondent must be afforded no less than five (5) business days from receipt of the Inquiry Memorandum to provide any comments in writing. Any comments submitted must be attached to the Inquiry Memorandum.

(c) If requested, the sections of the Inquiry Memorandum that relate to the informant's allegation(s), and only such sections, are to be made available to the informant solely for informational purposes.

17. JOINT VA/NON-VA INQUIRY LED BY VA:

a. **Applicability.** This paragraph applies to research misconduct inquiries for which it has been determined that a VA facility and a non-VA institution have joint procedural jurisdiction over the research misconduct allegation, a joint inquiry will be convened, and VA will lead the joint inquiry.

b. **Purpose.** The sole purpose of an inquiry initiated pursuant to this paragraph is to provide a preliminary assessment of readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation. See paragraph 16b.

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c. **Standard.** A research misconduct allegation will be deemed to have "sufficient substance" to warrant an investigation if the inquiry determines that the readily available evidence would raise a reasonable suspicion of research misconduct. See paragraphs 16c(1) and 16c(2).

d. **Procedures.** Joint VA/non-VA inquiries led by VA and convened pursuant to this paragraph 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 17 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, etc.) do not apply unless and until a respondent is named during the course of an inquiry.*

(1) **Initiation.** The VA facility Director must appoint a committee to conduct an inquiry within ten (10) business days after receiving notice of ORO's determination that an inquiry is warranted. An inquiry is considered "initiated" at the time the individual or committee is appointed by the Director.

(2) **Required Time Frame.** See paragraph 16d(2).

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

(a) The chairperson and any other VA representatives on the committee must meet the requirements of paragraph 16d(3)(b).

(b) At least one representative from 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) must be nominated by the non-VA institution with concurrence by the VA facility Director.

2. The non-VA representative(s) must not have any unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The non-VA representative(s) must participate as full member(s) of the joint Inquiry Committee including making a determination about whether the allegation has sufficient substance to warrant an investigation.

4. The non-VA representative may not be appointed Chair of the committee.

(c) In addition to the applicable requirements in paragraph 16d(3)(c), the written appointment letter must indicate that a joint inquiry is being convened, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, and specify that VA will lead the joint inquiry under the procedures of this Handbook.

(4) **Sequestration of Evidence.** See paragraph 16d(4).

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(5) **Notifications.** See paragraph 16d(5). In addition, the notifications to the respondent and informant must indicate that a joint inquiry is being convened, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, specify the name and position of the non-VA representative(s), and indicate that VA will lead the joint inquiry under the procedures of this Handbook.

(6) **Interviews and Review of Evidence.** See paragraph 16d(6).

(7) **Inquiry Memorandum.** All of the requirements specified at paragraph 16d(7) apply. In addition,

(a) The joint Inquiry Memorandum must indicate that it represents a joint report of the VA facility and the participating non-VA institution, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, and specify that VA led the joint inquiry under the procedures of this Handbook.

(b) The joint Inquiry Memorandum and submitted comments, if any, from the respondent, must be transmitted to the participating non-VA institution with joint procedural jurisdiction within five (5) business days of the deadline for receipt of the respondent's comments. If the participating non-VA institution with joint procedural jurisdiction requests copies of evidentiary exhibits cited in the Inquiry Memorandum, copies of the exhibits may be provided to the extent permitted by policy and law.

18. JOINT VA/NON-VA INQUIRY LED BY A NON-VA INSTITUTION:

a. **Applicability.** This paragraph applies to research misconduct inquiries for which it has been determined that a VA facility and a non-VA institution have joint procedural jurisdiction over the research misconduct allegation, a joint inquiry will be convened, and the non-VA institution will lead the joint inquiry.

b. **Purpose.** The purpose of a joint inquiry convened pursuant to this paragraph must not be inconsistent with the purpose set forth at paragraph 16b (i.e., to provide a preliminary assessment of readily available evidence to determine whether a research misconduct allegation has sufficient substance to warrant an investigation).

c. **Standard.** The standard for deeming whether a research misconduct allegation has sufficient substance to warrant an investigation must not be inconsistent with the standard set forth at paragraph 16c (i.e., that a research misconduct allegation must be deemed to have "sufficient substance" to warrant an investigation if the inquiry determines that the readily available evidence would raise a reasonable suspicion of research misconduct).

d. **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 FR 76260.

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(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 facility RIO (see paragraph 15d).

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

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

(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 Handbook's procedures as a condition of VA participating in a joint inquiry led by the non-VA institution. All modifications must be effected as early in the process as possible, timely notice of modifications deemed to be substantive by either ORO or the non-VA institution must be provided to the respondent, and the Inquiry Report must summarize all substantive procedural modifications.

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

(a) The VA representative(s) must be nominated by the VA facility Director with concurrence by the non-VA institution. At least one VA representative must hold a 5/8^{ths} or greater paid appointment at the VA facility and have experience conducting research.

(b) The VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses.

(c) The VA representative(s) must participate as full member(s) of the joint Inquiry Committee including making a determination about whether the allegation has sufficient substance to warrant an investigation.

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

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

19. VA DISPOSITION OF THE INQUIRY MEMORANDUM: The following steps must be taken when the Inquiry Memorandum (or its equivalent if a joint inquiry is conducted and the joint inquiry is led by a non-VA institution) is issued and any comments by the respondent are received and attached:

a. The Inquiry Memorandum, attachments, and evidentiary exhibits (as defined in VA Handbook 0700) must be forwarded to the VA facility Director and ORO.

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(1) If the Inquiry Memorandum recommends that an investigation be opened, an investigation must be convened according to paragraphs 20, 21, or 22, as applicable.

(2) If the Inquiry Memorandum recommends that an investigation not be opened for any or all of the allegation(s), the VA facility Director or ORO or both may nonetheless require that an investigation be convened according to paragraphs 20, 21, or 22, as applicable. Such a decision by the VA facility Director or ORO is within their full discretion insofar as that decision is not inconsistent with any other part of this Handbook. The justification for convening an investigation in spite of a contrary recommendation by the inquiry must be documented in writing and retained according to the applicable records control schedule.

(3) If the Inquiry Memorandum recommends that an investigation not be opened and both the VA facility Director and ORO concur with that recommendation, the research misconduct case is to be terminated.

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

(b) The VA facility leadership must provide reasonable assistance in restoring the respondent's reputation according to paragraph 12k.

(c) The case file must be retained by the VA facility according to the applicable records control schedule. See paragraph 6l.

(d) The informant may file a subsequent allegation of research misconduct, but only if the informant submits substantively new allegation(s) or evidence. The procedures for processing such allegations are set forth at paragraph 14d.

20. VA-ONLY INVESTIGATION:

a. **Applicability.** This paragraph applies only to research misconduct investigations for which it has been determined that VA has sole institutional jurisdiction over the research misconduct allegation, or for which all non-VA institutions with joint procedural jurisdiction have indicated that they do not wish to participate in a joint investigation with VA.

(1) The initiation or completion of an independent, non-VA investigation of the same research misconduct allegation does not negate the requirement to conduct a separate, VA-only investigation under this paragraph.

(2) A VA-only investigation may consider as evidence any proffered findings of a non-VA investigation of the same research misconduct allegation in addition to but not in lieu of evidence collected and analyzed by the VA-only Investigation Committee under this paragraph.

b. **Purpose.** The purpose of an investigation convened pursuant to this paragraph is to investigate and make recommended findings about whether and to what extent research

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misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the definition and evidentiary standard at paragraph 3.

c. **Procedures.** VA-only investigations convened pursuant to this paragraph must adhere to the following procedures. ***NOTE:*** *A VA research misconduct investigation constitutes an Administrative Investigation under VA Handbook 0700 and must follow all requirements of that Handbook except to the extent that any provision of this paragraph contradicts a provision of VA Handbook 0700 (see paragraph 6b). In all VA-led research misconduct investigations, the provisions of this Handbook take precedence over any contrary provision of VA Handbook 0700.*

(1) **Convocation.** The VA facility Director must convene an investigation of all research misconduct allegations forwarded for investigation by issuing a charge letter per paragraph 20c(4). An investigation is considered "initiated" at the time the charge letter is issued. If the Inquiry Memorandum recommended that an investigation be opened, the charge letter must be issued within ten (10) business days of the Director's receipt of the Inquiry Memorandum. If the Inquiry Memorandum recommended that an investigation not be opened and the Director or ORO do not concur with the recommendation, the charge letter must be issued within ten (10) business days of either the Director's or ORO's decision to require that an investigation be opened.

(2) **Multiple Respondents.** If more than one respondent is named, the VA facility Director must decide, within ten (10) business days of receipt of the Inquiry Memorandum (or subsequent addition of a respondent), whether to convene one investigation for all respondents or convene separate investigations for each respondent.

(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 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 facility Director with assistance of the RIO and the ORO-RMO 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 will apply separately to each investigation, including separate charge letters, separate Investigation Committees, separate case files, and separate Investigation Reports. No committee member of one investigation may be appointed as a committee member of another on-going investigation. The RIO may oversee multiple, ongoing investigations, but must maintain confidentiality of the information for each separate investigation.

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(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 facility Director. ***NOTE:*** *See paragraphs 20c(9)(d),(e), and (f) for required timeframes to complete drafts of the Investigation Report.*

(b) The addition of new allegations and/or respondents during the course of an investigation does not automatically change the original time frame for completion of the investigation. However, the VA facility Director may request an extension if necessary according to paragraph 20c(3)(c).

(c) If an extension of the time frame is required, the VA facility Director must submit a written request for extension to the ORO-RMO as early as possible but at least five (5) business days prior to the deadline for completing the investigation, providing a justification for the extension and a proposed extension period. ORO may grant an extension at its discretion.

(4) **Director's Charge Letter; Investigation Committee Appointment.** As the Convening Authority, the VA facility Director must issue a charge letter in accordance with VA Handbook 0700 and the following requirements.

(a) The Director must appoint an Investigation Committee of between three (3) to five (5) employees of the VA facility who have the ability to review, analyze, and form conclusions about relevant evidence according to this paragraph in an objective and timely manner.

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 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 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 5c) with respect to the research in question, the respondent, the informant, or other key witnesses. ***NOTE:*** *In the event that a potential conflict of interest between a committee member and a witness is identified during the course of an investigation, the issue must be reported to the facility Director, who will serve as the arbiter of whether a conflict of interest exists. In the event that the Director determines that a conflict of interest exists, the Director must either implement a mechanism for appropriately managing the conflict of interest (e.g., instructing that the committee member be recused from questioning the individual during interviews) or, in the event that the conflict of interest cannot be managed, removing the member from the committee.*

3. The Director must designate one member to serve as the chairperson of the Investigation Committee. The chairperson must hold at least a 5/8^{ths} paid appointment at the VA

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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 the committee.

5. With the exception of the RIO (see paragraph 20c(4)(a)4), individuals appointed to conduct the inquiry may also be appointed as members of the Investigation Committee.

6. If the VA facility Director is unable to identify enough qualified individuals from within the VA facility to comprise the minimum number of three (3) Investigation Committee members, otherwise qualified candidate(s) must be appointed from another VA facility within the same VISN, subject to the agreement of the other VA facility's Director.

(b) The Director's charge letter, in addition to the requirements specified in VA Handbook 0700, must include the names and positions of the members appointed to the Investigation Committee including specification of the Chair, the name of the respondent(s), a specific description of the allegation(s) to be reviewed in the investigation, the research and funding involved (to the extent known), the purpose and evidentiary standard of the investigation as set forth in paragraphs 20b and 3b, respectively, the required time frame for completion of the investigation, and the RIO's contact information. ***NOTE:*** *The research misconduct Investigation Committee may not be charged with investigating issues beyond research misconduct as defined in paragraph 3a.*

(c) The Director's charge letter must specify that the investigation must be conducted in accordance with this Handbook, that the Investigation Report must be in the standard format outlined in VA Handbook 0700, and that the Investigation Committee must make recommended findings about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate.

(d) If additional allegations of research misconduct arise during the course of the investigation, ORO must be notified in accordance with paragraph 14d(3) and, if required, the allegations added to the scope of the investigation. When such allegations are added to the investigation, the Director's charge letter must be amended to include the new allegations. ***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 course of the investigation, the Director's charge letter must be amended to include the new respondents. ***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.*

(f) The Director's charge letter, and any amendments thereto, must be copied to the ORO-RMO, the relevant VISN Director, any institution with joint procedural jurisdiction over the allegation, and any non-VA funding source as required by applicable regulation or policy.

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(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.

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

(a) The Respondent. The notification to the respondent must include the investigation's purpose and applicable standard, a specific description of the allegation(s) to be reviewed, the research and funding involved, the name and position of the members appointed to the Investigation Committee including specification of the Chair, and the RIO's contact information. The notification must either reference an applicable VHA Web site where this Handbook is posted or include an electronic or hardcopy attachment of the Handbook.

1. 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.

2. The notification must offer the respondent an opportunity to object to the appointment of any committee member based on a conflict of interest. The respondent may submit a written objection within three (3) business days of receiving the notification. Any written objection must be retained as part of the case record. The final decision to retain or replace Investigation Committee members belongs to the VA facility Director. If the Director decides to replace a committee member, the charge letter must be amended to reflect the change.

(b) The informant. The notification to the informant must include the name of the respondent(s) against whom the informant made the allegation, a specific description of the allegation(s) submitted by the informant to be reviewed in the investigation, the investigation's purpose and applicable standard, the name and position of the members appointed to the Investigation Committee including specification of the Chair, and the RIO's contact information.

1. 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.

2. The notification must offer the informant an opportunity to object to the appointment of any committee member based on a conflict of interest. The informant may submit a written objection within three (3) business days of receiving the notification. Any written objection must be retained as part of the case record. The final decision to retain or replace Investigation Committee members belongs to the VA facility Director. If the Director decides to replace a committee member, the charge letter must be amended to reflect the change.

(c) If and when any additional allegations and/or respondents are later added to the investigation per paragraphs 20c(4)(d) and 20c(4)(e), the VA facility Director must provide notification of such to the foregoing individuals in accordance with the provisions of paragraph 20c(6).

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(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 to include setting the schedule of committee activities and delegating tasks as needed to accomplish the objectives of the charge letter. The RIO must provide administrative and management support to the Chair and the committee.

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

(c) Minutes of committee meetings are not required; however, a chronology of the committee's activities must be documented and made part of the case record.

(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 committee physically present (i.e., not participating by video/teleconferencing, etc.), including the Chair.

(e) All final recommendations of the Investigation Committee, including split decisions, must include the participation of all appointed members of the committee.

(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 provision. ***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 Director's charge letter. This will include review of the Inquiry Memorandum and its attachments, relevant evidentiary exhibits from the inquiry, and all other collected evidence relevant to the allegations.

(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 the course of an investigation, the Investigation Committee through the RIO must notify ORO in accordance with paragraph 14d(3).

1. If ORO determines that the additional allegation may be added to the scope of the investigation, the charge letter must be amended to include the new allegation. Otherwise, the new allegation must not be added to the scope of the investigation.

2. To determine the extent of research misconduct, the Investigation Committee may conduct a review of those aspects of the respondent's research portfolio that are related to the research referenced in the allegation(s) being investigated. However, unless there is a reasonable suspicion of additional research misconduct, the Investigation Committee should not conduct an

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exhaustive review of the respondent's entire research portfolio and publications in order to pursue all instances of possible research misconduct other than that involving or related to the research referenced in the allegation(s) specified in the charge letter.

(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, preferably in that order, if available.

(e) Other witnesses who the committee determines are likely able to provide relevant documentary and/or testimonial evidence must be individually interviewed if available. The informant and/or respondent may suggest that other specific witnesses be interviewed, but the final decision to interview any particular witness belongs solely to the committee.

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

(g) All investigation interviews must be recorded and transcribed. 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 recommended findings in the Investigation Report.

(i) After fully reviewing and analyzing all of the relevant evidence and testimony that are reasonably available, the Investigation Committee must formulate recommendations for each allegation about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the definition and evidentiary standard at paragraph 3.

(j) 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 committee may <u>not</u> make any recommended <u>conclusions</u> about research impropriety or noncompliance <u>other than</u> research misconduct. However, the committee <u>may</u> make <u>findings of fact</u> regarding research noncompliance or impropriety but only insofar as such findings of fact are relevant to conclusions about research misconduct. Similarly, the committee may <u>not</u> recommend corrective actions for research impropriety or noncompliance <u>other than</u> research misconduct; however, the committee <u>may</u> recommend that identified noncompliance issues be referred to other appropriate VA entities for resolution.

(l) Recommendations of corrective actions, if any, must be made in accordance with paragraph 6i.

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

(a) The Investigation Report must contain the following elements: the name and position of the respondent(s); a detailed summary of the allegation(s); and the research and funding involved. For each allegation, the Investigation Report must indicate:

1. The basis for why the allegation falls within the scope of this Handbook (see paragraph 4a);

2. Recommended findings about whether and to what extent research misconduct has occurred, and who is responsible, based on the standard set forth at paragraph 3b;

3. The evidence reviewed;

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

5. A response to any contrary evidence including but not limited to the respondent's affirmative defenses; and

6. What corrective actions, if any, are appropriate.

(b) 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 Handbook 1058.04.

(c) The Investigation Report must be in standard format in accordance with VA Handbook 0700 and the Director's charge letter. An index (list) identifying the evidentiary exhibits cited in the report must be prepared in accordance with VA Handbook 0700 and the index will be considered to be part of the report. ***NOTE:*** *For the purposes of this Handbook, the actual evidentiary exhibits referenced in the report are not considered to constitute part of the report itself.*

(d) 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. If requested, administrative attachments to the report and cited evidentiary exhibits (as described in VA Handbook 0700) must be transmitted to ORO and/or OGC.

NOTE: *Unless an extension has been granted, the time frame for completing a research misconduct investigation is 120 days. Thus, in the absence of an extension, the draft report must be transmitted to the ORO-RMO and OGC within 60 days of the date the investigation was "initiated."* ORO and OGC will provide procedural comments, if any, on the draft report within 15 days of receipt. Upon receipt and consideration of the responses to the draft report, the Investigation Committee must revise the draft report, as appropriate, prior to sending it to the respondent and making it available to the informant for review (see paragraph 20c(9)(e) and (f)).

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(e) A draft of the Investigation Report must be transmitted to the respondent at least 40 days prior to the end of the allotted time frame for completing the investigation. ***NOTE:*** *Unless an extension has been granted, the time frame for completing a research misconduct investigation is 120 days. Thus, in the absence of an extension, the draft report must be transmitted to the respondent within 80 days of the date the investigation was "initiated."* The respondent must be afforded no less than 30 days from receipt of the draft report to provide any comments in writing. Upon receipt of the draft Investigation Report, respondents must be given reasonable access, as determined by the RIO, to all sequestered evidence supporting the proposed findings of research misconduct and proposed corrective actions, if any, for the purpose of preparing comments to the draft report.

(f) At the time the draft Investigation Report is transmitted to the respondent, the informant must be notified of the opportunity to review solely those sections of the draft report that relate to the informant's allegation(s). Reasonable access (e.g., timing, frequency, etc.) to review the draft report will be determined by the RIO. The informant must be afforded no less than 30 days from receipt of the notification to provide any comments in writing.

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

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

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

(j) The final Investigation Report and accompanying attachments and exhibits must be transmitted to the VA facility Director within the allotted time frame for completing the investigation.

21. JOINT VA/NON-VA INVESTIGATION LED BY VA:

a. **Applicability.** This paragraph applies to research misconduct investigations for which it has been determined that the VA facility and a non-VA institution have joint procedural jurisdiction over the research misconduct allegation, a joint investigation will be convened, and VA will lead the joint investigation.

b. **Purpose.** The purpose of an investigation convened pursuant to this paragraph is to investigate and make recommended findings about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the definition and evidentiary standard at paragraph 3.

c. **Procedures.** Joint VA/non-VA investigations led by VA and convened pursuant to this paragraph must adhere to the following procedures. ***NOTE:*** *A VA-led, joint research misconduct investigation constitutes an Administrative Investigation under VA Handbook 0700*

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and must follow all requirements of that Handbook except to the extent that any provision of this paragraph contradicts a provision of VA Handbook 0700 (see paragraph 6b). In all VA-led research misconduct investigations, the provisions of this Handbook take precedence over any contrary provision of VA Handbook 0700.

(1) **Convocation.** The VA facility Director must convene a joint investigation of all research misconduct allegations forwarded for investigation by issuing a charge letter per paragraph 21c(4). The charge letter must be issued within ten (10) business days of the Director's receipt of a VA or joint VA/non-VA Inquiry Memorandum recommending that an Investigation be opened, or within ten (10) business days of completion of a non-VA institution's independent inquiry into the same allegations if applicable, whichever is later. If the VA or joint VA/non-VA Inquiry Memorandum recommended that an investigation not be opened and the Director or ORO do not concur with the recommendation, the charge letter must be issued within ten (10) business days of either the Director's or ORO's decision to require an investigation.

(2) **Multiple Respondents.** See paragraph 20c(2).

(3) **Required Time Frame.** See paragraph 20c(3).

(4) **Director's Charge Letter; Investigation Committee Appointment.** All of the requirements specified at paragraph 20c(4) apply. In addition,

(a) At least one representative from 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 facility Director.

2. The non-VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses.

3. The non-VA representative(s) must participate as full member(s) of the joint Investigation Committee including making recommended findings of research misconduct and corrective actions.

4. The non-VA representative may not be appointed as Chair of the committee.

(b) The Director's charge letter must indicate that a joint investigation is being convened, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, include the name and position of the non-VA representative(s), and specify that VA will lead the joint investigation under the procedures of this Handbook.

(5) **Sequestration of Evidence.** See paragraph 20c(5).

(6) **Notification of Investigation.** All of the requirements specified at paragraph 20c(6) apply. In addition, the notifications to the respondent and informant must indicate that a joint

investigation is being convened, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, include the name and position of the non-VA representative(s), and specify that VA will lead the joint investigation under the procedures of this Handbook.

(7) **Committee Actions.** See paragraphs 20c(7) and 21c(4)(a)3.

(8) **Interviews and Review of Evidence.** See paragraph 20c(8).

(9) **Joint Investigation Report.** All of the requirements specified at paragraph 20c(9) apply. In addition,

(a) The joint Investigation Report must indicate that it represents a joint report of the VA facility and the participating non-VA institution, provide the basis for the participating non-VA institution's joint procedural jurisdiction over the allegation, and specify that VA led the joint investigation under the procedures of this Handbook.

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

22. JOINT VA/NON-VA INVESTIGATION LED BY NON-VA INSTITUTION:

a. **Applicability.** This paragraph applies to research misconduct investigations for which it has been determined that the VA facility and a non-VA institution have joint procedural jurisdiction over the research misconduct allegation, a joint investigation will be convened, and the non-VA institution will lead the joint investigation.

b. **Purpose.** The purpose of a joint investigation convened pursuant to this paragraph must not be inconsistent with the purpose set forth at paragraph 20b (i.e., to investigate and make recommended findings about whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate, based on the definition and evidentiary standard at paragraph 3).

c. **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 facility RIO (see paragraph 15d).

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

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

(3) VA, including ORO, and the non-VA institution may agree upon modifying the non-VA institution's procedures to incorporate specific elements of this Handbook's procedures as a condition of VA participating in a joint investigation led by the non-VA institution. All modifications must be effected as early in the process as possible, timely notice of modifications deemed to be substantive by either ORO or the non-VA institution must be provided to the respondent, and the Investigation Report must summarize all substantive procedural modifications.

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

(a) The VA representative(s) must be nominated by the VA facility Director with concurrence by the non-VA institution. At least one VA representative must hold a 5/8^{ths} or greater paid appointment at the VA facility and have experience conducting research.

(b) The VA representative(s), like all other members appointed to the committee, must not have any unmanageable conflicts of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses.

(c) The VA representative(s) must participate as full member(s) of the joint Investigation Committee including making recommended findings of research misconduct and corrective actions.

(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 Investigation Report and submitted comments, if any, from the respondent and informant (as applicable), must be transmitted to the Director of the VA facility with joint jurisdiction within five (5) business days of issuance of the report or five (5) business days of the deadline for receipt of comments, if any, whichever is later.

23. VA DISPOSITION OF THE INVESTIGATION REPORT:

a. **Applicability.** This paragraph applies to all research misconduct Investigation Reports completed under this Handbook including those produced by a VA-only investigation and those produced by a joint VA/non-VA investigation.

b. **VA Facility Director Certification.** Within ten (10) business days of receiving a research misconduct Investigation Report, the VA facility Director must certify completion of the investigation on behalf of VA. Within the 10-business day time frame,

(1) The VA facility Director must review the Investigation Report.

(2) The VA facility Director must include with the certificate of completion a concurrence or non-concurrence with each of the Investigation Report's recommended findings and corrective actions, may make additional recommended findings and corrective actions, and must provide a written rationale for each non-concurrence and added recommendation. ***NOTE:*** *For joint investigations led by the non-VA institution, the VA facility Director must only provide concurrence or non-concurrence with recommended findings and corrective actions that fall within the scope of this Handbook (see paragraph 4).*

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

(4) The VA facility Director must transmit to ORO the certificate of completion and two copies of the Investigation Report with administrative attachments and evidentiary exhibits (as defined in VA Handbook 0700) appended to each copy of the report. The facility must retain at least one additional copy of the Investigation Report with appended evidentiary exhibits and attachments in accordance with the relevant records control schedule. See paragraph 6l.

c. **ORO Procedural Review.** ORO must review the Investigation Report and the VA facility Director's certificate of completion for procedural conformance with this Handbook.

(1) ORO will 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, provided that evidence is cited to support each recommendation for a finding of research misconduct.

(2) 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 Handbook 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 3a). ***NOTE:*** *If the Investigation Report was produced by a joint VA/non-VA investigation led by a non-VA institution, ORO's procedural review will assess the process used to address the research misconduct allegations under VA's jurisdiction for adherence to the basic procedural requirements of the Federal Policy on Research Misconduct.*

(a) If ORO determines that that the procedural requirements have been satisfied, ORO will transmit the following to the relevant VISN Director for Adjudication: ORO's procedural determination; one copy of the Investigation Report with appended evidentiary exhibits and attachments; and the VA facility Director's certificate of completion.

(b) If ORO determines that any procedural requirements have not been satisfied, it must further assess whether the procedural noncompliance is of such magnitude and consequence so

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as to materially affect the outcome of the case. ORO must document its determination and include all evidence that supports the determination.

1. If ORO determines that the failure to adhere to the procedural requirements set forth in this Handbook did not materially affect the outcome of the case, ORO must transmit the following to the relevant VISN Director for Adjudication: ORO's procedural determination; one copy of the Investigation Report with appended evidentiary exhibits and attachments; and the VA facility Director's certificate of completion.

2. If ORO determines that the failure to adhere substantially to the procedures set forth in this Handbook materially affected the outcome of the case, ORO will either request that the VA facility Director reopen the investigation using the same committee or 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 paragraph 20, 21, or 22, whichever is applicable, will 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 both the VA facility Director and VISN Director. Once the re-opened or *de novo* investigation is completed, the VA facility Director must transmit to ORO the certificate of completion and two copies of the Investigation Report along with administrative attachments and evidentiary exhibits (as defined in VA Handbook 0700) appended to each copy of the report. ORO must then conduct a procedural review of the re-opened or *de novo* investigation in accordance with paragraph 23c(2).

(3) If a Governmentwide debarment has been recommended, ORO must also determine whether the recommendation is procedurally sufficient per VHA Handbook 1058.04. If it determines that the debarment recommendation is not procedurally sufficient, ORO may return the case to the VA facility Director for appropriate action.

(4) ORO's procedural review of the case should normally be completed within 45 days from receipt of case documents transmitted by the VA facility Director in accordance with paragraph 23b(4), or receipt of additional information or clarifications requested by ORO to complete its review, whichever is later. If an extension of the time frame is required, ORO must submit a written request for an extension to the Under Secretary for Health as early as possible, but at least five (5) business days prior to the deadline for completing the procedural review.

24. VETERANS INTEGRATED SERVICE NETWORK DIRECTOR ADJUDICATION:

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

b. **Purpose.** The purpose of a VISN Director Adjudication under this paragraph is to make a VA decision, based on recommendations from the investigation, as to whether research

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misconduct occurred; and if so, a decision as to the type and extent of misconduct, the responsible individual(s), and the appropriate corrective actions.

c. **Procedures.** Adjudications initiated under this paragraph must adhere to the following procedures.

(1) **Responsibility.** The requirements assigned to the VISN Director in paragraph 24 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 personally by the VISN Director.

(a) The VISN Director may not designate any person, who has an unmanageable conflict of interest (see paragraph 5c) with respect to the research in question, the respondent, the informant, or other key witnesses to perform any of the procedures described in paragraph 24.

(b) If, as determined by the Under Secretary for Health, 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 ORO as an alternate Adjudicator.

(2) **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 ORO-RMO as early as possible but at least five (5) business days prior to the deadline for completing the Adjudication, providing a justification for the extension and a proposed extension period. ORO will grant an extension at its discretion.

(3) **Review of Evidence.** The VISN Director must thoroughly review the Investigation Report including attached exhibits, the VA facility Director's certificate of completion, and ORO's procedural determination.

(a) 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.

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

(c) The VISN Director may consult with ORO, OGC, or any other person or office with relevant knowledge or expertise.

(4) **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.

(a) The decision must be consistent with the research misconduct definition and evidentiary standard in paragraph 3.

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

(c) If the Investigation Committee and/or VA facility Director recommended a Governmentwide debarment, the adjudication must either concur or not concur with the recommendation.

d. **Disposition.** The VISN Director must transmit the final decision memorandum to ORO.

(1) If the VISN Director's decision memorandum makes any findings of research misconduct, the following steps will be taken:

(a) ORO must provide written notification to the respondent of the findings and corrective actions, as well as the respondent's opportunity to appeal under paragraph 25. A copy of the final Investigation Report, the VA facility Director's certificate of completion of the investigation, and the VISN Director's decision memorandum must accompany ORO's notification.

(b) ORO must provide written notification to the informant of those findings pertaining to the allegations made by the informant, as well as the corrective actions to be imposed.

(c) ORO must provide written notification of the findings and corrective actions to ORD and any Federal entity that has joint oversight jurisdiction over the allegation.

(d) ORO must provide written notification of the findings and corrective actions to the VA facility Director. A copy of the VISN Director's decision memorandum must accompany ORO's notification to the VA facility Director.

(e) To the extent not already provided by ORO (see paragraph 24d(1)(c)), the VA facility Director must provide a copy of ORO's written notification of the findings and corrective actions to any non-VA entity with joint procedural jurisdiction over the allegation (e.g., academic affiliate) and any non-VA funding source if such notification is required by applicable regulation or policy.

(f) ORO must provide to the Under Secretary for Health written notification of the findings and corrective actions. A copy of the Investigation Report, ORO's procedural review of the case (see paragraph 23c), the VA facility Director's certificate of completion of the investigation, and the VISN Director's decision memorandum must accompany ORO's notification to the Under Secretary for Health.

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

(a) ORO must provide written notification of the VISN Director's decision to any Federal entity that has joint oversight jurisdiction over the allegation.

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(b) ORO must transmit the VISN Director's decision memorandum to the VA facility Director.

(c) The VA facility Director must provide written notification of the case closure to the respondent and informant. To the extent not already provided by ORO (see paragraph 24d(2)(a)), the VA facility Director must provide written notification of the case closure to any non-VA entity with joint procedural jurisdiction over the allegation (e.g., academic affiliate) and any non-VA funding source if such notification is required by applicable regulation or policy.

(d) The VA facility leadership must provide reasonable assistance in restoring the respondent's reputation according to paragraph 12k.

(e) The case file must be retained by the VA facility according to the applicable records control schedule (see paragraph 6l).

25. APPEAL AND DEBARMENT PROCEEDINGS:

a. **Applicability.** This paragraph applies only to appeals of research misconduct findings and corrective actions imposed by a VISN Director's Adjudication under paragraph 24d(1), and to VISN Director recommended Governmentwide debarments under paragraph 24c(4)(c). Only named respondents may appeal findings of research misconduct and corrective actions under this paragraph. Neither the informant nor any party other than the respondent has a right to appeal a finding or non-finding of research misconduct.

b. **Debarment Recommendations.** If the VISN Director recommended a Governmentwide debarment under paragraph 24c(4)(c), the procedures for issuing and contesting a proposed debarment are set forth at VHA Handbook 1058.04.

(1) If the respondent contests a Governmentwide debarment proposed by the Under Secretary for Health under VHA Handbook 1058.04, those procedures will also constitute an appeal of the research misconduct findings and other corrective actions under this paragraph.

(2) The additional fact-finding procedures applicable to proposed debarments under VHA Handbook 1058.04 do not apply to any research misconduct appeal under this paragraph that does not include a proposed Governmentwide debarment.

c. **All Other Research Misconduct Appeals.** Appeals of research misconduct findings and corrective actions under this paragraph must adhere to the following procedures:

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

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

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(b) The respondent's submission must include the notice of research misconduct finding, the final Investigation Report, the precise research misconduct findings and/or corrective actions that are being appealed, a statement of the grounds for the appeal, and any additional evidence that supports the grounds for appeal.

(c) Three complete, collated copies of the appeal must be submitted.

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

(2) **Review of Appeal.** The Under Secretary for Health or designee will review all appeals that are timely and complete.

(a) The Under Secretary or designee will review all documents submitted by the respondent by the required deadline (see paragraph 25c(1)), documents submitted by ORO, and any other relevant information.

(b) OGC, ORO, and other Departmental resources may be consulted for advice.

(c) The Under Secretary may request additional information or clarifications from the Investigation Committee, VA facility personnel, and/or the VISN Director. The Under Secretary may also request that the Investigation Committee provide additional analysis.

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

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

(b) The Final Agency Decision must include a justification for upholding, reversing, or modifying the VISN Director's Decision Memorandum. ***NOTE:*** *An appeal of a finding of research misconduct on the basis of noncompliance with the procedures set forth in this Handbook will not be grounds for reversing the finding unless the magnitude and consequence of such noncompliance are determined by the Under Secretary to have materially affected the outcome of the case.*

(c) The Final Agency Decision must be consistent with the definition and evidentiary standard at paragraph 3.

(d) The Under Secretary's final written decision should normally be completed within 45 days from receipt of all submissions, information, and findings of fact.

(4) **Notifications.** ORO forwards the Final Agency Decision issued by the Under Secretary for Health to the respondent, with copies to the VISN Director, and the VA facility Director.

(a) ORO must provide written notification of the case closure to ORD and any Federal entity that has joint oversight jurisdiction over the allegation.

(b) To the extent not already provided by ORO (see paragraph 25c(4)(a)), the VA facility Director must provide written notification of the case closure to the informant, any non-VA

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institution with joint procedural jurisdiction over the allegation, and any non-VA funding source if such notification is required by applicable regulation or policy.

(5) **Decision to Reverse all Findings.** If the Under Secretary for Health reverses all findings of research misconduct, leadership at the VA facility must provide reasonable assistance in restoring the respondent's reputation according to paragraph 12k.

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

26. REFERENCES:

a. Title 5 U.S.C. §1201 Notes, et seq., Whistleblower Protection Act of 1989.

b. Title 5 U.S.C. §552, Freedom of Information Act.

c. Title 5 U.S.C. §552a, Privacy Act of 1974.

d. Title 2 CFR Part 801, Subpart B, Department of Veterans Affairs Implementation of OMB Guidance on Nonprocurement Debarment and Suspension.

e. Title 38 CFR §§ 1.200 – 1.205, [Employee's Duty to Report and] Referrals of Information Regarding Criminal Violations.

f. Title 38 CFR §0.735-12(b), Standards of Conduct in Special Areas.

g. Title 42 CFR Part 93, Public Health Service Policies on Research Misconduct.

h. 65 FR 76260, Federal Policy on Research Misconduct.

i. VA Handbook 5021, Employee/Management Relations.

j. VA Handbook 0700, Administrative Investigations.

k. VHA Directive 1058, The Office of Research Oversight.

l. VHA Directive 1200, VHA Research and Development Program.

m. VHA Handbook 1200.01, Research and Development (R&D) Committee.

n. VHA Handbook 1058.01, Research Compliance Reporting Requirements.

o. VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research.

p. VHA Handbook 1058.06, Research Conducted by Employees of VHA Program Offices.

q. VHA Handbook 1605.1, Privacy and Release of Information.

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r. VHA Records Control Schedule 10-1.

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