Policy Manual

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17. Policy on Research Misconduct

I. Introduction

A. *General policy*

The Chicago Association for Research and Education in Science (CARES) is committed to supporting the performance of scientific research with integrity and high ethical standards. CARES personnel are expected to exercise their integrity in carrying out their scientific activities and to provide reasonable supervision of those under their direction to ensure the integrity of the research being conducted. CARES has established the following policies and procedures to investigate and resolve alleged or apparent instances of misconduct in research.

B. Joint Jurisdiction

CARES shares jurisdiction over all CARES research activities with each of its VA affiliated facilities. CARES will coordinate its response to allegations of research misconduct with the VA site in order to maximize procedural uniformity and minimize duplication, while recognizing institutional autonomy.

CARES and its VA affiliated locations will make a good faith effort to conduct a joint inquiry and wherever possible a joint investigation in response to any allegation of research misconduct. The VA site may take the lead in conducting the response to an allegation of research misconduct. CARES will, in such an event, designate at least one representative to participate in the inquiry and investigation. If a mutual determination is made that CARES shall be the lead agency in an inquiry and investigation, the VA site will designate at least one VA site employee with research experience and at least 5/8ths status to be a full participant in the inquiry and investigation.

Each inquiry and investigation will result in a single set of recommendations, though a minority opinion may be included. After review by its Board of Directors, CARES will accept the findings and recommendations of the VA-led joint inquiries, investigations, and adjudications.

For investigators with VA and affiliated university faculty appointments (dual-appointment personnel), the university may exercise concurrent jurisdiction over research misconduct. As necessary, the appropriate personnel at each institution will be notified of scientific misconduct issues that arise. In addition, other agencies or entities that co-sponsor or otherwise support the research effort may also exert concurrent jurisdiction. Examples include, but are not limited to, the Public Health Service (PHS) of the Department of Health and Human Services (DHHS), in particular its Office of Research Integrity (ORI), the Department of Veterans' Affairs Office of Research Oversight (ORO), and the Food and Drug Administration (FDA). The VA Research Integrity Officer (RIO) must notify all agencies and entities that have joint jurisdiction over a research project of any allegation of misconduct regarding that research.

C. Scope of CARES Policy

This policy is applicable to allegations of research misconduct by CARES personnel in respect to a research project that is supported by or through CARES. In other cases, for example, an allegation regarding VA-funded research and VA staff alone, the handling of allegations of research misconduct is governed by the policy and procedures in VHA Handbook 1058.2 ("Research Misconduct") and VHA Handbook 0700 ("Administrative Investigations)".

D. Other Forms of Impropriety

This policy addresses allegations of research misconduct, defined as fabrication, falsification, and plagiarism of research proposals, data, or results (see Section II). Authorship disputes other than plagiarism are not covered in this policy. It does not deal with ethical lapses or other types of professional misconduct, such as misallocation of funds, harassment or discrimination, violation of laws or regulations established for the protection of human or animal subjects, or violations of other CARES, or VA policies, even if the alleged behavior involves or occurs in connection with research activity.

E. Confidentiality

To the extent allowed by law, CARES shall maintain the identity of respondents and whistleblowers securely and confidentially and shall not disclose any identifying information, except to:

1. Those who need to know it in order to carry out a thorough, competent, objective and fair research misconduct proceeding;
2. PHS's ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings;
3. VA's ORO as it conducts its oversight of the proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need access to it in order to carry out the research misconduct proceeding.

II. Definitions

A. Allegation means any written statement or other indication of possible scientific misconduct received by the RIO, whether directly or referred from the potential respondent's superior, CARES's Executive Director, or another source.

B. Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal, professional, or financial relationships. Any such conflict which a reasonable person would consider to demonstrate potential bias will disqualify a person for selection to serve in research misconduct proceedings.

C. Good faith allegation means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

D. Inquiry means gathering information and initial fact-finding solely to determine whether an allegation or other readily available evidence of scientific misconduct warrants an investigation.

E. Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person(s) and the seriousness of the misconduct.

F. ORI means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

G. ORO means the Office of Research Oversight, the office within the U.S. Department of Veterans Affairs that is responsible for scientific misconduct policies and activities within the VA health care system.

H. PHS means the U.S. Public Health Service, an operating component of the DHHS.

I. PHS regulation means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

J. PHS support means PHS grants, contracts, or cooperative agreements or applications for the same.

K. Research Integrity Officer (RIO) means the CARES or VA official responsible for receiving allegations of scientific misconduct, determining when such allegations warrant inquiries, and overseeing inquiries and investigations.

L. Research record means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

M. Respondent means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

N. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. “Fabrication” is making up data or results and recording or reporting them. “Falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. “Plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences in opinion or interpretation of data.

ORI has a broader definition of research misconduct which includes other practices that seriously deviate from those commonly accepted within the scientific community (see 42 CFR Section 93.102(b), attached). If an institutional proceeding does not find sufficient evidence of research misconduct as defined here, ORI may choose to independently review the case based on its own standard of research misconduct.

O. Retaliation means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

P. CARES Personnel means any person who is employed by CARES, is a CARES investigator, or serves as an officer of CARES.

Q. Whistleblower means a person who makes an allegation of scientific misconduct.

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

CARES will appoint the Research Integrity Officer for the institution who will have primary responsibility for implementing the procedures set forth in this document. The RIO will be a CARES investigator, officer, or employee who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith. Whenever feasible, CARES will appoint the local VA Research Integrity Officer as its own RIO.

The RIO will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will attempt to ensure that confidentiality is maintained. The RIO will consult and cooperate with those CARES and VA officers charged with responding to allegations of scientific misconduct in order to conduct a joint inquiry and investigation into such allegations.

The RIO will assist inquiry and investigation committees and all CARES and, VA personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of those files.

The RIO will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the RIO has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report; these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified of the final determinations and resulting actions. All such notices will be in written form. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of legal counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation. If the respondent is found guilty of scientific misconduct, he or she has the right to appeal that finding and any proposed corrective measures.

D. Board of Directors

The CARES Board of Directors appoints the RIO, supports the conduct of any inquiries and investigations, and determines corrective measures to be applied to CARES personnel in the event of a finding of research misconduct. Respondents may appeal findings of research misconduct or proposed corrective measures to the Board of Directors. The Board of Directors may also direct CARES to take actions to restore a respondent's reputation or to protect a whistleblower from possible retaliation.

E. VA Director

The Director of the local VA site will receive the inquiry report and any written comments made by the respondent or whistleblower on the draft report, and determine based on those materials whether to proceed to conduct an investigation of the allegation.

The associated VA Directors are also *ex officio* members of the CARES Board of Directors.

F. VISN Director

The VISN Director will receive the investigation report and any written comments made by the respondent or the whistleblower on the draft report. The VISN Director will consult with the RIO or other appropriate officials and will determine if misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions (see section X).

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All CARES personnel should report observed, suspected, or apparent misconduct in science to the RIO. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the RIO at (708) 202-5353 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, CARES personnel may have confidential discussions and consultations about concerns of possible misconduct with the Executive Director or the RIO and will be counseled about appropriate procedures for reporting allegations.

Any formal allegation of research misconduct that is received by a CARES investigator, officer, or employee must be referred to the RIO.

B. Protecting the Whistleblower and Others

The RIO will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in good faith with inquiries or investigations. The RIO will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status and will review instances of alleged retaliation for appropriate action.

CARES personnel should immediately report any alleged or apparent retaliation to the RIO.

CARES will also protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the whistleblower requests anonymity, CARES will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed. CARES will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. *Protecting the Respondent*

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or the thoroughness of the inquiry or investigation.

CARES personnel accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. The counsel or advisor may not speak for or on behalf of the respondent during the inquiry or investigation.

D. Cooperation with Inquiries and Investigations

CARES personnel will cooperate with the RIO and other officials in the review of allegations and the conduct of inquiries and investigations. CARES personnel have an obligation to provide relevant evidence to the RIO and other designated officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether PHS support, PHS applications for funding, or research records as defined in 42 CFR Section 93.102(b) (see attached) are involved, and whether the allegation falls under the CARES and/or VA definitions of scientific misconduct. If the allegation fails to meet any of these threshold requirements, the RIO will notify the whistleblower that a research misconduct case will not be opened and provide an explanation of which threshold requirement was not met and to what other, if any, jurisdiction or procedure it is appropriate to direct the allegation.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up and falls under the definition of scientific misconduct provided above, he or she will immediately initiate the inquiry process. In initiating the inquiry, the RIO will clearly identify the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is <u>not</u> to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

The following persons will be provided written notification of the misconduct allegation and the opening of an inquiry: the respondent(s), the whistleblower, the VA Director, ORO, the Executive Director of CARES, and any other entity with joint jurisdiction, such as ORI.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science, the RIO will take all reasonable and practical steps to ensure that all original research records and materials relevant to the allegation are immediately inventoried and secured. The RIO may consult with ORI for advice and assistance in this regard.

Reasonable, supervised access to, or copies of, the original data may be provided to the respondent so that he or she can continue the research prior to the completion of a misconduct proceeding.

C. Appointment of the Inquiry Committee

The RIO, in consultation with other CARES or VA officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee will consist of individuals who do

not have real or apparent conflicts of interest with the respondent, whistleblower, potential witnesses, or others involved in the matter, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside CARES or the VA facility. The inquiry committee will include representatives of both CARES or the VA facility as appropriate.

The RIO will notify the respondent of the proposed committee membership in 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible. At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

The resources and advice of ORI are available to the RIO and committee members in formulating and conducting the inquiry process.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the source(s) of research support and the identity of sponsors (for example, NIH or another federal agency, nonprofit foundations, voluntary health organizations such as the American Heart Association, or others); a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether and investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Whistleblower

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with a summary of the inquiry findings or portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation, so that the whistleblower may comment thereon.

1. Confidentiality

   The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report

2. Receipt of Comments

   Within 14 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by the VA Directors

The RIO will transmit the final report and any comments to the appropriate VA Director, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. If the RIO, inquiry committee, and/or the local VA Directors find that available evidence is sufficient to justify opening an investigation, an investigation must be opened (see section VII). The inquiry is completed when the VA Director makes this determination, which will be made within 30 days of the first meeting of the inquiry committee.

2. Notification

The RIO will notify both the respondent and the whistleblower in writing of the decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify CARES's Executive Director and other appropriate CARES, appropriate officials of the VA Director's decision.

The RIO will also provide ORI with the final report and a copy of CARES, the VA site's institutional policies and procedures for research misconduct. If the inquiry committee's decision is not to investigate the allegation, ORI may perform an oversight review of the determination not to investigate, and will be provided access to all relevant materials to conduct its review.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing no more than 30 calendar days following its first meeting, unless the RIO and ORO approve an extension for good cause. If an extension is approved, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. Conducting the Investigation

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public, or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The RIO will immediately take all reasonable and practical efforts to take custody of any additional pertinent research records and evidence that was not previously sequestered during the inquiry. This sequestration will occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including a decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Reasonable, supervised access to, or copies of, the original data may be provided to the respondent so that he or she can continue the research prior to the completion of a misconduct proceeding.

C. Appointment of the Investigation Committee

The RIO, in consultation with other officials of CARES and the VA as appropriate, will appoint an investigation committee and the committee chair within 10 days of the recommendation to open an investigation. The investigation committee will consist of at least three individuals who do not have real or apparent conflicts of interest with the respondent, whistleblower, potential witnesses, or others involved in the matter, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. The inquiry committee will include representatives of CARES and the VA site. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The RIO will notify the respondent and whistleblower of the proposed committee membership within 5 days. If either the respondent or whistleblower submits a written objection to any appointed member of the investigation committee or expert on the basis of conflict of interest, the RIO and local VA Director will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The RIO, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, PHS regulations and procedures.

E. *Investigation Process*

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. The committee will interview each respondent, whistleblower, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. All interviews will be transcribed or recorded. Transcripts or recordings will be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

The burden of proof of research misconduct is on the institution: a preponderance of evidence must be found to be present in order to arrive at a conclusion of research misconduct. The committee must decide by consensus whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions. If a consensus cannot be reached on one or more of these questions, the Investigation Report must note the area(s) of disagreement, the arguments supporting and opposing the various viewpoints, and the majority opinion, if any.

The resources and advice of ORI are available to the RIO and committee members in formulating and conducting the inquiry process.

VIII. The Investigation Report

A. Elements of the Investigation Report

The final report will:

1 Describe the nature of the allegations of research misconduct and the specific allegations considered in the investigation

2 Describe and document all grantor support related to the allegation of research misconduct, e.g., grant numbers, grant applications, contracts, or publications listing the grantor's support;

3 Describe the policies and procedures under which the investigation was conducted;

4 Identify and summarize the evidence and research records reviewed, including any relevant records and evidence either taken into custody but not reviewed or not taken into custody;

5 State and explain the findings as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found:

i. Identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard;

ii. Summarize the facts and analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations;

iii. Identify the specific source of support, whether PHS, a different federal agency, or other;

iv. Identify any publications that require correction or retraction;

v. Identify the person(s) responsible for the misconduct;

vi. List any current or known applications or proposals for support that the respondent(s) has pending with federal agencies other than PHS;

6. Include and consider any comments made by the respondent and whistleblower on the draft investigation report;

7. Describe any sanctions imposed and administrative actions taken by CARES or the VA site.

B. Comments on the Draft Report

The draft report will be provided for comment as provided in this policy, VA policy and procedures, and 42 CFR Section 93.312.

1. Respondent

The RIO will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 7 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report will take into account the respondent's comments in addition to all the other evidence.

2. Whistleblower

The RIO will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report may be modified, as appropriate, based on the whistleblower's comments.

3. Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments will be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

Within 7 days of receiving the final report, the VA Director must certify completion of the joint CARES-VA site investigation and transmit the final investigation report, with all supporting documents, to the VISN Director. The VA sitel Director may include additional recommendations when he forwards the final investigation report from the RIO to the VISN Director for adjudication.

C. *Institutional Review and Decision*

Based on a preponderance of the evidence, the VISN Director will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the VISN Director will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The VISN Director's explanation will be consistent with the CARES and VA definitions of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The VISN Director may also return the report to the investigation committee with a request for further fact-finding or analysis. The VISN Director's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the RIO will notify both the respondent and the whistleblower in writing. In addition, the VISN Director will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The RIO will also ensure the Executive Director of CARES is notified of the VISN Director’s conclusions.

D. Appeal by the Respondent

Respondents against whom a finding of research misconduct is made have the opportunity to appeal that finding, and corrective measures proposed by the VA, to the Under Secretary of Health. Such appeals are governed by the procedures laid out in the VHA Handbook 1058.2 Section 19.

Respondents have the opportunity to appeal corrective measures proposed by CARES to the CARES Board of Directors.

E. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the RIO will transmit the final report with attachments, including the respondent's and whistleblower's comments and the VISN Director's adjudication, to ORI. ORI will conduct its own oversight review of the results of the proceeding. ORI may accept the findings and conclusions in part or in whole; request additional information or investigation; reject the report and conduct its own investigation; impose administrative sanctions on the respondent beyond those identified by the VISN Director; or take other actions within its authority. CARES and the RIO, with the advice of counsel, will cooperate with ORI requests in such an event.

F. Time Limit for Completing the Investigation Report

An investigation will ordinarily be completed within 90 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the VISN Director for approval, and submitting the report to ORI. An extension to this period may be granted by ORO.

If the investigation will not be completed within 120 days, the RIO must notify ORI and request an extension (see Section IX below).

IX. Requirements for Reporting to ORI

The decision to initiate an investigation must be reported in writing to the Director of ORI, on or before the date the investigation begins. At a minimum, the notification will include the name of the person(s) against whom the allegations have been made, a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a) (see attached), and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of CARES, local VA policies and procedures will be explained in any reports submitted to ORI.

If it is decided to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

If the investigation committee, CARES or the VA site determines that it will not be able to complete the investigation in 120 days, the RIO will submit to ORI a written request for an extension that explains the delay, reports on the progress to date,

estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.

If CARES or the VA site plan to terminate an inquiry or investigation prior to the completion of all steps laid out in this policy, the RIO will notify ORI of the planned termination and the reasons for the decision. ORI will review the information provided and advise whether further steps should be undertaken.

When an admission of scientific misconduct is made, the RIO will contact the sponsor(s) providing financial or other support for the research in question for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

The RIO will notify ORI at any stage of the inquiry or investigation if:

1. there is an immediate health or safety hazard involved, including an immediate need to protect human or animal subjects;

2. there is an immediate need to protect Federal funds or equipment;

3. there is an interim decision that research activities should be suspended;

4. there is an immediate need to protect the interests of those involved in the research misconduct proceeding;

5. it is probable that the alleged research misconduct or the research misconduct proceeding will prematurely be made public;

6. there is a determination by CARES or the VA site that the research community or the public should be informed; or

7. there is reasonable indication of a possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

X. Institutional Actions

CARES or the VA site will take administrative actions against individuals and other appropriate corrective actions when an allegation of misconduct has been substantiated.

If the VISN Director determines that the alleged misconduct is substantiated by the findings, the Board of Directors of CARES will, after consultation with the VISN Director, RIO, and the CARES Executive Director as appropriate, decide on the appropriate actions to be taken with regard to CARES employment, CARES-supported research, and other CARES resources.

These actions may include, but are not limited to: withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found, removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment, or restitution of funds as appropriate.

Any such actions are separately determined and may be in addition to those taken by the VA site in the course of its adjudication. VA procedures for determining and applying appropriate disciplinary actions are treated in VHA Handbook 5021.

DHHS may impose administrative actions as a result of its own finding of research misconduct, as set forth in 42 CFR Section 93 (see attached). Such actions are separate from and additional to those imposed by CARESthe and the VA. CARES and the VA site will cooperate with and assist ORI and DHHS as needed to carry out any actions imposed as a result of a final finding of research misconduct by DHHS.

XI. Other Considerations

A. Termination of Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's CARES employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry but after an allegation has been reported or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, CARESand the VA site will undertake all reasonable, practical, and appropriate efforts to restore the respondent's reputation. Depending on

the particular circumstances, the RIO will consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any actions on the part of CARES to restore the respondent's reputation must first be approved by the Board of Directors.

C. Protection of the Whistleblower and Others

Regardless of whether the institution or ORI determines that scientific misconduct occurred, CARES or its VA affiliated facility will undertake all reasonable and practical efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the VISN Director will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. If the whistleblower is CARES personnel, he or she may also consult with CARES's Executive Director and/or Board of Directors to determine what steps, if any, are needed to restore his or her position and reputation. The RIO is responsible for implementing any steps the Board of Directors or the VISN Director approves.

The RIO and Executive Director will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith

If relevant, the VISN Director will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the VISN Director will determine whether any administrative action will be taken against the whistleblower.

E. Interim Protective Actions

At any time during a research misconduct proceeding, CARES and its VA affiliated site will take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

F. Referral of Other Misconduct

An inquiry or investigation may find evidence of misconduct or impropriety that does not fall under the heading of research misconduct defined in this policy. In such cases and where PHS support is involved, the RIO and any inquiry or investigative committee is obligated to refer the allegation as follows:

1. In case of possible criminal activity, to the Office of the Inspector General at DHHS;

2. In case of possible violation of human subjects protection regulations, to the Office of Human Research Protection at DHHS;

3. In case of possible violation of animal subjects protection regulations, to the Office of Laboratory Animal Welfare at NIH;

4. In case of possible violation of FDA regulations, to the Office of Regulatory Affairs at FDA;

5. In case of possible fiscal irregularities or improprieties, to the Office of Management Assessment at NIH (where NIH grants or contracts are concerned) or the Office of Grants and Contracts at PHS (where non-NIH resources of PHS are concerned).

XII. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for seven years after completion of the proceeding or of any ORI or DHHS proceeding under Subparts D and E of 42 CFR Part 93 (see attached), whichever is later, unless custody of said file or records has been transferred to DHHS or ORI has advised that the records no longer need be retained.

In addition, upon notice to the local VA site or CARES, the VA Office of Research Oversight (ORO) has the right to inspect or sequester research records related to a misconduct allegation, inquiry, or investigation.

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