

NUMBER: 1426

TITLE: Policy, Procedures and Timeline for Responding to Allegations of Misconduct in Scientific Research and Scholarly Activity

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I. Introduction

A. General Policy

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II. Definitions

- A. Allegation means any written statement of possible misconduct made to an institutional official, either to the dean of the affected college or to the Research Integrity Officer (“RIO”).
- B. Complainant means a person who makes an allegation of misconduct in scientific research or other scholarly activity.
- C. Confidentiality means a state or quality of being confidential. It connotes the entrustment with secret affairs or purpose and a shared intent to operate secretly. In many cases of research misconduct, confidentiality is a legal requirement. Each member involved in the process bears the duty of protecting the privacy of both the Complainant and the Respondent; a member who breaches this duty may be subject to discipline.
- D. 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 or professional relationships.
- E. Day means calendar day.
- F. Deciding Official “DO” means the university official who makes final determinations on allegations of misconduct and any responsive institutional actions. The DO will

expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of 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; exhibitions, productions, or displays; correspondence; videos; photographs; X-ray film; slides; biological materials; audio-tape recordings; 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.

- T. Respondent means the person against whom an allegation of 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.
- U. 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 misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.
- V. Sequester means to separate or isolate documents or material from the individual concerned and into the custody of a disinterested institutional official designated by the RIO, such as the general counsel, who can provide confidential and secure storage.

III. Rights and Responsibilities

A. Research Integrity Officer

The president will appoint the RIO, who will have primary responsibility for implementation of the procedures set forth in this document. The RIO will be an institutional official 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. In general, the provost and vice president for academic affairs, general counsel, and vice president for research are unavailable for service as the 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 investigation. The RIO will ensure that confidentiality is maintained.

The RIO will assist the inquiry and investigation committees and all institutional 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 the files.

The RIO, through the vice president for research¹, will report to ORI or NSF, as required by regulation, keep the appropriate agency apprised of any developments during the course of the investigation that may affect current or potential funding for the individual(s) under investigation or that the agency needs to know to ensure appropriate use Federal funds, and otherwise protect the public interest.

B. Complainant

The Complainant 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 Complainant may be able to provide pertinent information on any portions of the draft report, ft report, s d88ertinent

D. Deciding Official “DO”

The DO will receive the inquiry and investigation reports and any written comments made by the Respondent or the Complainant on the draft report. The DO will decide whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Old Dominion University should report observed, suspected, or apparent misconduct to the RIO directly or through the dean of the affected college. If an individual is unsure whether a suspected incident falls within the definition of misconduct, he or she may informally and

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 thoroughly carrying out the inquiry or investigation.

Institutional employees accused of 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.

D. Cooperation with Inquiries and Investigations

All individuals involved will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. This affirmative duty includes the obligation to provide relevant evidence to the RIO or other officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of misconduct, the RIO will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS or NSF support or applications for funding are involved, and whether the allegation falls under the PHS or NSF definitions of scientific misconduct.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

The RIO, in consultation with other university officials as appropriate, will normally interview the Complainant, the Respondent, and key witnesses as well as examine relevant research records and materials. The RIO will evaluate the evidence and testimony and decide whether there is sufficient evidence of possible misconduct to recommend further investigation.

The RIO will submit a draft report to the DO, Complainant and Respondent that describes his/her conclusion regarding sufficient evidence of possible misconduct that would justify further investigation. The RIO will establish reasonable conditions for review to protect the confidentiality of the draft report.

Within 10 days of their receipt of the draft report, the Complainant and Respondent will provide their comments, if any, to the RIO. Any comments that the Complainant or Respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the RIO may revise the draft report as appropriate.

The RIO will transmit the final report and any comments to the DO who will have 10 days in which to make the determination of whether findings from the inquiry provide sufficient evidence of possible misconduct to justify conducting an investigation. The inquiry is completed when the DO makes this determination, which will be made within 60 days of the RIO's commencement of the Inquiry. Any extension of this period will be based on good cause and recorded in the inquiry file.

The RIO will notify both the Respondent and the Complainant in writing of the DO's 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 the president, the general counsel, the vice president for research, and the dean of the affected college or other university unit.

VI. 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. The findings of the investigation will be set forth in an investigation report.

of the final report should take into account the Respondent's comments in addition to all the other evidence.

2. Complainant

The RIO will provide the Complainant, if he or she is identifiable, with those portions of the draft Investigation Report that address the Complainant's role and opinions in the investigation. The Complainant will be allowed 10 days to review and comment on that part of the draft report provided by the RIO. The report should be modified, as appropriate, based on the Complainant's comments.

3. General Counsel

The draft investigation report will be transmitted to the General Counsel for a review of its legal sufficiency. The General Counsel's comments should be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and will 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.

C. Final Report

After comments have been received and the necessary changes have been made to the draft report, the Investigation Committee should transmit the final report with attachments, including the Respondent's and Complainant's comments, to the DO, through the RIO. The final report, if applicable, will be submitted through the Office of Research to ORI and/or NSF.

D. Institutional Review and Decision

Based on a preponderance of the evidence, the DO will make the final determination whether to accept the Investigation Report, its findings, and the recommended institutional actions. The DO may also return the report to the Committee with a request for further fact-finding or analysis. The DO's determination together with the Investigation Committee's report, constitute the final investigation report for purposes of agency review. If the DO's final determination varies from that of the Investigation Committee, the DO 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 PHS (ORI), NSF, or other funding agency. The DO's explanation should be consistent with the particular agency's definition of misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee.

The DO will also notify both the Respondent and the Complainant in writing. In addition, the DO 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.

VIII. Requirements for Reporting to ORI or NSF Inspector

- A. The decision to initiate an investigation of PHS- or NSF-funded research must be reported in writing, through the Office of Research, to the director of ORI (at DHHS) or the Inspector General of NSF before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the definition of misconduct, and the agency applications or grant number(s) involved. ORI or NSF 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 these policies and procedures should be explained in any reports.
- B. Prior to any decision to terminate an inquiry or investigation without completing all relevant requirements of the PHS or NSF regulations, the RIO, through the Office of Research, will submit a report of the planned termination to ORI or the NSF Inspector General, including a description of the reasons for the proposed termination.
- C. If the university determines that it will not be able to complete an Inquiry and Investigation of federally funded research in 120 days, the RIO will submit to the respective agency a written request for an ext

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 the respective agency concurs, after consulting with the Respondent, the RIO will undertake reasonable efforts to restore the Respondent's reputation. Depending on the particular circumstances, the RIO should 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 misconduct was previously publicized, or expunging all reference to the misconduct allegation from the Respondent's personnel file. Any institutional actions to restore the Respondent's reputation must first be approved by the DO.

C. Protection of the Complainant and Others

Regardless of whether the institution, ORI or NSF determines that misconduct occurred, the RIO will undertake reasonable efforts to protect Complainants who made allegations of misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the DO will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The RIO is responsible for implementing any steps the DO approves. The RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the Complainant.

D. Allegations Not Made in Good Faith

The DO will determine whether the Complainant's allegations of misconduct were made in good faith. If an allegation was not made in good faith, the DO will determine whether any administrative action should be taken against the Complainant.

E. Interim Administrative Actions

The Vice President for Research will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out.

XI. 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 transfer the file to the Provost and Vice President for Academic Affairs, for safekeeping, who will maintain the file for three years after completion of the case to permit later

assessment of the case. ORI, NSF, or other authorized personnel will be given access to the records upon request.

APPENDIX

This appendix summarizes the responsibilities assigned to the DO and the RIO. The appendix is a review of the duties assigned to these two officials.

Responsibilities of the DO

- Determines whether an investigation is warranted
- Determines whether to accept the investigation report
- Determines institutional administrative actions if misconduct is found
- Explains why the institution does not agree with the investigation report, if such is the case, in a transmittal letter to ORI or NSF
- Determines institutional administrative actions against "bad faith" Complainants
- Informs ORI or NSF that an investigation is not warranted, if such is the case, if the agency requested the inquiry

Responsibilities of the RIO

- Receives allegations of misconduct
- Receives allegations of retaliation
- Receives reports of "bad faith" allegations
- Receives reports of violations of PHS or NSF regulations

Assessment of Allegations

- Conducts preliminary assessment of allegations
- Determines whether an inquiry is warranted
- Refers non-scientific misconduct issues to appropriate institutional or Federal office

Conduct of Inquiry

- Initiates inquiry process
- Notifies appropriate institutional officials, the Respondent, and, if necessary, the appropriate agency that an inquiry is underway
- Sequesters research or other relevant records
- Conducts the inquiry
- Determines whether additional expertise is needed
- Establishes conditions of confidentiality
- Protects against bias or conflicts-of-interest
- Develops the charge
- Meets ORI or NSF notification requirements
- Takes appropriate interim administrative actions
- Seeks advice from federal agencies when an admission of misconduct is made
- Determines whether a time extension will be allowed

Provides a draft report to the Respondent
Provides appropriate portions of the draft report to Complainant
Transmits the final report and comments to the DO
Communicates the decision of the DO to the Complainant, and Respondent.
Notifies ORI or NSF if an investigation will be conducted
Provides the final report and inquiry file to ORI or NSF upon request, if relevant
Retains all inquiry records
Reports "bad faith" allegations to the DO
Undertakes reasonable efforts to restore the reputation of cleared

INQUIRY & INVESTIGATION PROCEDURES

TIMELINE	STEPS
Day 1 Inquiry Begins	<p>RIO determines sufficient evidence of possible misconduct in scientific research or scholarly activities.</p> <p>RIO immediately secures all original research records and materials relevant to the allegation. RIO may consult with federal agencies through Office of Research</p>
Days 2-29	

	member of the Investigation Committee. The RIO will immediately replace the first challenged member and determine whether to replace the other challenged members or experts with qualified substitutes.
Day 75	First meeting of the Investigation Committee.
Days 76-100	Investigation Committee conducts its examination of evidence and submits a draft report of its findings to the RIO.
Day 101	RIO provides Respondent with copy of draft Investigating Committee report for comment and rebuttal. RIO provides Complainant with those portions of the draft report that address the Complainant's role and evidence/testimony.
Day 110	Deadline for Respondent and Complainant to submit to the Investigating Committee comments and rebuttal on the draft report.
Day 113	Investigating Committee transmits its final report with attachments, including the Respondent's and Complainant's comments, to the DO, through the RIO.
Day 120 Investigation Ends	<p>Based on the preponderance of the evidence, the DO will make the final determination. If this determination varies from that rendered by the Investigating Committee, the DO will provide a full explanation.</p> <p>Deadline for completion of the Investigation if PHS or NSF funded activities. If has not been completed by this day, the RIO must submit to ORI and/or NSF 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. The request will be submitted through the Office of Research. DO will also notify the Respondent and Complainant in writing of the final determination.</p>