NUMBER: 1427

TITLE: Procedures for Responding to Allegations of Misconduct in Scientific Research or Other Scholarly Activity

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I. Introduction

These procedures provide the methods and principles for assessing allegations and conducting inquiries and investigations related to possible misconduct in scientific research or other scholarly activity; in particular, these procedures seek compliance with misconduct procedures for scientific research that is proposed to or supported by the U.S. Public Health Service or the National Science Foundation. Included are procedures for reporting scientific misconduct investigations to these agencies, adopting institutional actions in response to findings of scientific misconduct, and cooperating with the PHS Office of Research Integrity (ORI) or the NSF Inspector General in their review of institutional actions and reports. Hereafter, "research" connotes any type of scientific research or other scholarly activity and "misconduct" connotes misconduct in scientific research or in other scholarly activity.

These procedures are intended to govern the assessment of allegations, the conduct of inquiries and investigations, and the reporting of results to the appropriate agency. The procedures do not create any right or benefit, substantive or procedural, enforceable at law by a party against the institution, its agencies, officers, or employees.

These procedures should be read in conjunction with the Old Dominion University Policy for Responding to Allegations of Misconduct in Scientific Research and Scholarly Activity.

II. Definitions

A. *Allegation* means any written statement of possible misconduct in scientific research or other scholarly activity made to an institutional official, either the dean of the affected college or to the research integrity officer.

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. This definition is not intended to conflict with or replace the State and Local Government Conflict of Interests Act of the Code of Virginia 2.1-639.1 through 2.1-639.24 (as amended from time to time).

E. *Deciding Official* means the university official who makes final determinations on allegations of misconduct and any responsive institutional actions. The deciding official will normally be the provost and vice president for academic affairs. For this reason, he or she cannot serve as the research integrity officer. If the provost had direct, prior involvement in the research, inquiry, or allegation assessment, he or she must recuse him or herself and the president will appoint an alternate deciding official.

F. *Employee* or *member* means, for the purpose of these instructions only, any person paid by, under the control of, or affiliated with Old Dominion University, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

G. *General Counsel* means legal counsel who represents Old Dominion University during the misconduct inquiry and investigation and who is responsible for advising the research integrity officer, the inquiry and investigation committees, and the deciding official on relevant legal issues. The general counsel does not represent the respondent, the complainant, or any other person participating during the inquiry, investigation, or any follow-up action, except the university officials responsible for managing or conducting the misconduct process as part of their official duties.

H. *Good faith allegation* means an allegation made with the honest belief that 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.

I. *Inquiry* means information-gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

J. *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 and the seriousness of the misconduct.

K. Old Dominion University defines *misconduct in scientific research and other scholarly activity* as:

1. fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for

proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

2. the retaliation against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith. (In such cases, agency notification is limited to the NSF.)

3. Misconduct in scholarly activity connotes any form of attribution of another's work as the respondent's own work.

The ODU definition is based on how Research Misconduct is defined in the regulations promulgated by the National Science Foundation and Public Human Service.

L. *NSF* means the National Science Foundation.

M. *NSF regulation* means the National Science Foundation regulation establishing standards for institutional inquiries and investigations into allegations of misconduct, which is set forth at 45 C.F.R. Part 689, entitled "Misconduct in Science and Engineering."

N. *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.

O. *PHS* means the U.S. Public Health Service, an operating component of the U.S. Department of Health and Human Services.

P. *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 Possible Misconduct in Science."

Q. *PHS or NSF support* means PHS or NSF grants, contracts, or cooperative agreements, or applications therefore.

R. *Research Integrity Officer* means the institutional official responsible for assessing allegations of misconduct, for determining when such allegations warrant inquiries, and for overseeing any inquiries and investigations.

S. *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 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; exhibitions, productions, or displays; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; audio-tape recordings; 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 who is 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 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 research integrity officer, such as the general counsel, who can provide confidential and secure storage.

III. General Procedures 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 research integrity officer directly or through the dean of the affected college. The research integrity officer will promptly engage in an assessment of the allegation to determine whether it falls within the definition of misconduct, involves PHS or NSF support, and provides sufficient information to proceed with an inquiry.

B. Protecting the Complainant

Employees who receive or learn of an allegation of misconduct will treat the complainant with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect against retaliation the position and reputation of the complainant and other individuals who cooperate with Old Dominion University. Employees will immediately report any alleged or apparent retaliation to the research integrity officer.

C. Protecting the Respondent

Employees who receive or learn of an allegation of misconduct will treat the respondent with fairness and respect. The research integrity officer will take reasonable steps to ensure that the process observes these procedural safeguards, the PHS regulation, 42 C.F.R. Part 50, Subpart A, and the NSF regulation, 45 C.F.R. Part 689. Employees will report significant deviations from these instructions to the research integrity officer. The research integrity officer will report any allegation not made in good faith to the deciding official for appropriate action.

D. Confidentiality

Institutional employees who make, receive, or learn of an allegation of misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the complainant, the respondent, and other affected individuals. The research integrity officer may establish reasonable conditions, such as confidentiality agreements, to ensure the confidentiality of such information.

E. Responding to Allegations

In responding to allegations of misconduct, the research integrity officer and any other institutional official with an assigned responsibility for handling such allegations will make diligent efforts to ensure that the following functions are performed.

1. Any allegation assessment, inquiry, or investigation is conducted in a timely, objective, thorough, and competent manner.

2. Reasonable precautions are taken to maintain confidentiality and avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation.

3. Immediate notification is provided to the PHS (ORI) or NSF (Inspector General) if:

    a. there is an immediate health hazard involved;

    b. there is an immediate need to protect federal funds or equipment;

    c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

d. it is probable that the alleged incident is going to be reported publicly;

e. the allegation involves a sensitive public health issue, e.g., a clinical trial;

f. there is a reasonable indication of a possible Federal criminal violation. In this instance, the institution must report within 24 hours of obtaining that information;

g. for any other reason, the scientific community or the public should be informed.

3. Interim administrative actions are taken, as appropriate, to protect federal funds and the public health, and to ensure that the purposes of the federal financial assistance are carried out.

F. Employee Cooperation

Employees will cooperate with the research integrity officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the research integrity officer or other institutional officials on misconduct allegations. Further, employees will cooperate with ORI or NSF in its conduct of inquiries and investigations, its oversight of institutional inquiries and investigations, and any follow-up actions.

G. Evidentiary Standards

The following evidentiary standards apply to findings of misconduct in research and scholarly activity.

1. Burden of Proof - The burden of proof for making a finding of misconduct is on the university.

2. Standard of Proof - Any finding of misconduct will be established by a preponderance of the evidence. This means that the evidence shows that it is more likely than not that the respondent committed misconduct in scientific research or scholarly activity.

H. Completion of Process

The research integrity officer is responsible for ensuring that the inquiry investigation process and all other steps required by this investigation and the PHS

or NSF regulations are completed even in those cases where the respondent leaves after allegations are made.

I. Early Termination

If circumstances suggest the termination of an inquiry or investigation into PHS- or NSF-funded research prior to completion of all the steps required by the PHS or NSF regulations, the research integrity officer, through the Office of Research, will notify the respective agency of the planned termination and the reasons therefore. The agency will then review the information provided and advise the institution whether further investigation should be undertaken.

J. Referral of Non-Scientific Misconduct Issues

When the institution's review of the allegation identifies non-scientific misconduct issues, the research integrity officer should refer these matters to the proper institutional, state, or federal office for action. Some of the issues meriting referral are described below.

1. Criminal Violations - Potential violation of criminal law under DHHS grants and contracts should be referred to the Office of Inspector General, DHHS-OIG Hot line, 330 Independence Avenue, SW, Washington, D. C. 20201, telephone (800) 447-8477. If the possible criminal violation is identical to the alleged scientific misconduct (e.g., alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG. Potential violation of criminal law under NSF grants and contracts should likewise be referred to the Office of the Inspector General, NSF, 4201 Wilson Boulevard, Arlington, VA 22230, telephone (703) 292-7100.

2. Violation of Human and Animal Subject Regulations - Potential violation of human subject regulations should be referred to the Office for Human Research Protection, 1101 Wootton Parkway, Rockville, MD 20852, telephone (301) 496-7005 or (866) 447-4777. Potential violations of the Animal Welfare Act should be referred to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, Eastern Region, Animal Care, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606, telephone (919) 855-7100.

3. Violation of FDA Regulations - Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, Room 12A41, Rockville, MD 20857, telephone (301) 827-3101.

4. Fiscal Irregularities - Potential violations of cost principles or other fiscal irregularities should be referred as follows:

   a. For all NIH Agencies-Office of Management Assessment, NIH, 6011 Executive Blvd., Suite 601, Rockville, MD 20852, MSC 7669. Telephone (301) 496-1873, FAX: (301) 435-1901, email:manuals@od.nih.gov: URL: http://OMA.OD.NIH.GOV.

   b. For all other PHS Agencies-PHS Office of Grants and Contracts, 5600 Fishers Lane, Room 5C18, Rockville, MD 20857, telephone (301) 443- 6557.

   c. For NSF-Office of the Inspector General, NSF, 4201 Wilson Boulevard, Arlington, VA 22230, telephone (703) 292-7100. Email Chris Boesz at cboesz@nsf.com.

   If there are any questions regarding the proper referral of non-scientific misconduct issues, the research integrity officer may call the ORI Division of Investigation Oversight at (301) 443-5330, or the NSF Inspector General at (703) 292-7100, to obtain advice.

K. Requirements for Reporting to Federal Agencies

1. The decision to initiate an investigation into PHS- or NSF-funded research must be reported in writing to the Director of ORI or the Inspector General of NSF on or 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's applications or grant number(s) involved. Notification to the NSF should further include a request for deferral of the NSF inquiry and investigation. The agency must 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 the institutional policies and procedures should be explained in any reports.

2. Prior to the decision, for any reason, to terminate an inquiry or investigation of PHS- or NSF-funded research without completing all relevant requirements of the PHS or NSF regulation, the research integrity officer will submit a report of the planned termination to the respective agency, including a description of the reasons for the proposed termination.

3. If at any time it appears that the university will not be able to complete the investigation in 120 calendar days, the research integrity officer will submit

to ORI 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. If the NSF is the funding agency, the Office of Research may authorize an extension of the investigation such that the investigation and all administrative actions will be complete within an additional 60 days. If the request is granted, the research integrity officer will file periodic progress reports as requested by the agency.

4. When PHS or NSF funding or applications for funding are involved and an admission of misconduct is made, the research integrity officer will contact the agency for consultation and advice. Normally, the individual making the admission of misconduct will be asked to sign a statement attesting to the occurrence and the extent of misconduct. When the case involves agency funds, the university will not accept an admission of misconduct as a basis for closing a case or not undertaking an investigation without prior approval from the agency.

5. When PHS or NSF funding is involved, the research integrity officer will notify ORI or NSF at any stage of the inquiry or investigation if:

   a. there is an immediate health hazard involved;

   b. there is an immediate need to protect federal funds or equipment;

   c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

   d. it is probable that the alleged incident is going to be reported publicly;

   e. the allegation involves a sensitive public health issue, e.g., a clinical trial;

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

   g. for any other reason, the scientific community or the public should be informed.

IV. Preliminary Assessment of Allegations

A. Allegation Assessment

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

1. PHS or NSF Support - Allegations involving research supported by PHS- or NSF-funded grants, contracts, or cooperative agreements, or applications for funding connote that agency's support. If the allegation does not involve agency support, it should be handled under the NSF definition of misconduct **(http://www.oig.nsf.gov/misconductmeansold.htm)** and procedures except that the reporting and compliance aspects of 42 C.F.R. Part 50, Subpart A or 45 C.F.R. Part 689 do not apply.

2. PHS Definition - The PHS definition of scientific misconduct is found in II. K.1 and 2, and II.P. The allegation should be carefully reviewed to determine whether it potentially constitutes fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices for proposing, conducting, or reporting research. In case of doubt, the research integrity officer should consult with the general counsel or ORI on whether the allegation falls within the PHS definition of scientific misconduct.

3. NSF Definition - The NSF definition (II.K.1 and II.M) adds to the PHS definition any retaliation against the reporting person or any person providing information.

4. Old Dominion University Definition - The Old Dominion University definition of scientific misconduct is based on the NSF definition and is found in II.K.1. and 2. The definition of misconduct in scholarly activity is found in II.K.3.

5. Sufficient evidence to proceed - There is not always sufficient evidence or information to permit further inquiry into the allegation. For example, an allegation that a scientist's (or scholar's) work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, an effort should be made to obtain more information before initiating an inquiry. This information may be sought from any reasonable source, including the complainant, if known.

B. Referral of Other Issues

Regardless of whether it is determined that a misconduct inquiry is warranted, if the allegation involves PHS or NSF support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation should be referred to the appropriate office. See section III.J.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the research integrity officer determines that the allegation provides sufficient information to allow specific follow-up and falls under the definition of misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the research integrity officer should identify clearly 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, complainant, and key witnesses to determine whether there is sufficient evidence of possible misconduct to warrant an investigation. The purpose of the inquiry is not 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.

B. First Steps if an Inquiry is Necessary

As soon as practicable after the research integrity officer determines that an inquiry is required, he or she will:

1. secure the relevant research records;

2. notify the Office of Research, the general counsel, the respondent, and if PHS or NSF funding is involved, the ORI or the Inspector General of NSF through the Office of Research. In the case of NSF funding, the notification should specifically include a request that NSF defer independent inquiry;

3. appoint and charge the inquiry committee; and

4. notify ORI or NSF if any of the conditions listed in section III.E.3 of these procedures are present.

The research integrity officer or general counsel may consult with an affected federal agency at any time regarding appropriate procedures to be followed.

C. Sequestration of the Research Records

1. Immediate Sequestration - If the relevant research records have not been obtained at the assessment stage, the research integrity officer will immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of records.

2. Institutional Access - Research records produced under PHS or NSF grants and cooperative agreements are the property of Old Dominion University, and employees cannot interfere with the university's right of access to them. Under some federal contracts, certain research records may belong to the federal agency, which will normally allow access to contract records in the custody of the university for purposes of reviewing misconduct allegations.

3. Original Records - The documents and materials to be sequestered will include all the original items (or copies if originals cannot be located) that may be relevant to the allegations. These include, but are not limited to, research records as defined in section II.S. of this document.

4. Sequestration of the Records from the Respondent - The research integrity officer should notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with location and identification of the research records. The research integrity officer should obtain the assistance of the respondent's supervisor and the general counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification. In addition to securing records under the control of the respondent, the research integrity officer may need to sequester records from other individuals, such as coauthors, collaborators, or complainants. As soon as practicable, and if requested, a copy of each sequestered record will be provided to the individual from whom the record is taken. These measures will be undertaken with care to preserve the confidentiality, privacy, and reputation of the respondent inasmuch as is reasonable during the sequestration.

5. Inventory of the Records - A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

6. Security and Chain of Custody - The research integrity officer will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of a university official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the general counsel.

D. Notification of the Respondent

1. Contents of Notification - The research integrity officer will notify the respondent in writing of the opening of the inquiry. The notification should identify the research project in question and the specific allegations; define misconduct; identify the presence, source, and implications of PHS or NSF funding; list the names of the members of the inquiry committee (if appointed) and experts (if any); explain the respondent's opportunity to challenge the appointment of a member of the committee or expert for bias or conflict of interest, to be assisted by counsel, to be interviewed, to present evidence to the committee, and to comment on the inquiry report; address the respondent's obligation as an employee of the institution to cooperate; describe the institution's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings.

2. Potential Respondents - If no specific respondent has been identified at this stage of the process, the research integrity officer will notify each potential respondent that an inquiry will be undertaken, e.g., each coauthor on a questioned article, each investigator on a questioned grant application, or each co-participant in other scholarly activity. The research integrity officer will consult with the general counsel on the proper method of notification under the circumstances.

E. Designation of an Official or a Committee to Conduct the Inquiry

The research integrity officer is responsible for conducting or designating others to conduct the inquiry.

1. Use of an Inquiry Committee - In complex cases, the research integrity officer will normally appoint a committee of three or more persons to conduct the inquiry, following the procedures set forth in section V.F. (see below).

2. Use of an Inquiry Official - In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the research integrity officer may choose to conduct the inquiry directly or designate another qualified individual to do so. In such cases, the inquiry official will nevertheless obtain the necessary expert and technical advice to consider properly all research issues.

3. Inquiry Process - The inquiry, whether conducted by a committee or an individual, will follow each procedural step set forth below.

F. Appointment of the Inquiry Committee

If an inquiry committee is to be appointed, the research integrity officer will use the following procedures.

1. Committee Membership - The research integrity officer, in consultation with other university officials as appropriate, will appoint the committee and committee chair within 10 calendar days of the initiation of the inquiry. The inquiry committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are believed to be fair and 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 of the institution.

2. Experts - The research integrity officer, in consultation with the committee, will determine whether additional experts other than those appointed to the committee need to be consulted during the inquiry to provide special expertise to the committee regarding the analysis of specific evidence. In this case, the experts provide a strictly advisory function to the committee; they do not vote and generally do not interview witnesses. The experts chosen may be from inside or outside of Old Dominion University.

3. Bias or Conflict of Interest - The research integrity officer will take reasonable steps to ensure that the members of the committee and experts have no bias or personal or professional conflict of interest with the respondent, complainant, or the case in question. In making this determination, the research integrity officer will consider whether the individual (or any members of his or her immediate family):

a. has any financial involvement with the respondent or complainant;

b. has been a coauthor on a publication with the respondent or complainant;

c. has been a collaborator or coinvestigator with the respondent or complainant;

d. has been a party to a research controversy with the respondent or complainant;

e. has a supervisory or mentor relationship with the respondent or complainant;

f. has a special relationship, such as a close personal friendship, kinship, or a professional/client relationship with the respondent or complainant; or

g. falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

4. Objection by Respondent - The research integrity officer will notify the respondent of the proposed committee membership within 10 calendar 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 five days, the research integrity officer will immediately replace the first challenged member or expert with a qualified substitute and determine whether to replace other members or experts the respondent challenges.

5. Confidentiality - Members of the committee and experts will agree in writing to maintain the confidentiality of the proceedings and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the research integrity officer to have knowledge of the inquiry.

6. Provision of Assistance - The research integrity officer, in consultation with the general counsel, will provide staff assistance and guidance to the committee and the experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report.

G. Charge to the Committee and the First Meeting

The research integrity officer 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, complainant, and key witnesses to determine whether there is sufficient evidence of possible misconduct to warrant an investigation pursuant to university, and PHS or NSF requirements if applicable. The purpose is not to determine whether misconduct definitely occurred or who was responsible.

At the committee's first meeting, the research integrity officer 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 research integrity officer and general counsel will be present or available throughout the inquiry to advise the committee as needed.

H. General Approaches to Conducting the Inquiry

During the inquiry, the committee will take the following steps.

1. The committee will collect information relevant to commonly accepted research practices of the community involved, the questioned practices at hand, and determine whether any credible information supports characterizing the questioned practices as misconduct. The scope of the inquiry is limited; the inquiry should not weigh a conflict in credible information, but refer it to investigation.

2. The committee will take all necessary steps to avoid bias or conflict of interest between the committee and experts and the respondent, complainant, and witnesses.

3. The committee will refer other issues that arise; it will advise the research integrity officer of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy. See section III.E.3 and III.J.

I. General Approaches to Conducting an Interview

1. Purpose of the Interview - The purpose of an interview at the inquiry stage is to allow each respondent, complainant, or witness to tell his or her side of the story. The committee should not attempt to speculate about what happened or might have happened or put words in the witnesses' mouths.

Also, the committee should not disclose information obtained from others interviewed unless this is necessary and can be done without identifying the source of the information.

2. Issues to Cover - Before an interview, the committee should provide each witness with a summary of the matters or issues intended to be covered at the interview. If the committee raises additional matters, the witness should be given an opportunity to supplement the record in writing or in another interview. The witness should be informed that his or her cooperation and truthful answers are expected.

3. Confrontation - Witnesses should not be told at this stage whether other testimony conflicts with theirs, although questions may be asked for purposes of clarifying the testimony. Avoid leading questions such as, "You must have made a mistake and thought it was actually this way, right?"

4. Using Experts - The committee may request that experts attend or participate in interviews to assist in its evaluation of the allegations and related issues. If the committee determines that such participation is not appropriate, it may ask an expert to prepare questions for the committee to use at the interview. Any expert retained to assist the committee may read the transcripts or summaries of the interviews.

5. Transcribing Interviews - Interviews with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or information. Changes to the transcript or summary will be made only to correct factual errors.

6. Confidentiality of Interviews - Witnesses should be advised that the proceedings are confidential and that they should not discuss the inquiry or their interview with anyone else other than their counsel or adviser.

7. Access to Counsel - Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or witness in the case. However, the counsel or adviser may only advise the witness and may not participate directly in the interview. Witnesses will respond directly to the interview questions.

8. Order of Interviews - The inquiry committee should interview, if possible, the complainant, key witnesses, and the respondent, in that order. Witnesses should be asked to provide, in advance if possible, any relevant evidence,

including their own notes, manuscripts, research records, or other documents that were not sequestered previously but are relevant to the allegation.

9. Interviewing the Complainant - In interviewing the complainant, the inquiry committee should attempt to obtain as much additional evidence regarding the substance of the allegation as possible and to determine the complainant's view of the significance and impact of the alleged misconduct. However, it is not the complainant's responsibility to prove his or her allegations.

10. Interviewing the Respondent - The respondent should be asked to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of scientific or professional judgment occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

11. Recording Admissions - If the respondent admits to the misconduct, the respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is a sufficient basis to proceed directly to an investigation. However, the admission may not be a sufficient basis for closing a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made when PHS or NSF funding is involved, the research integrity officer through the Office of Research, or the general counsel may seek advice from ORI or NSF in determining whether there is a sufficient basis to close a case, after the admission is fully documented and all appropriate procedural steps are taken. If the case is closed, the report should be forwarded to the deciding official with recommendations for appropriate institutional sanctions and then submitted to agency review, if relevant. If the respondent admits to the misconduct, the committee may consult with the general counsel immediately, with the option of seeking advice from ORI or NSF as needed.

12. Committee Deliberations - The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the research integrity officer and general counsel, the committee members will decide whether there is sufficient evidence of possible misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

    Committee deliberations should never be held in the presence of the interviewee. During the interview, the committee members should not debate among themselves or with witnesses over possible interpretations of

scientific research or other scholarly activity. These questions should be reserved for private discussions among the inquiry committee members and expert consultants.

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 presence and source of PHS or NSF or other support; 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 an investigation is warranted; 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. General counsel will review the report for legal sufficiency. All relevant dates should be included in the report.

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

The research integrity officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with those portions of the draft report that address the complainant's role and opinions in the investigation.

1. Confidentiality - The research integrity officer will 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 complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official - The research integrity officer will transmit the final report and any comments to the deciding official, who will 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 deciding official makes this determination, which will be made within 60 calendar days of the first meeting of the

inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification - The research integrity officer will notify both the respondent and the complainant in writing of the deciding official'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 research integrity officer will also notify all appropriate institutional officials of the deciding official's decision.

D. Time Limit for Completing the Inquiry Report

The draft report should be prepared within 36 calendar days in order to leave time for the inclusion of any comments into the final report and the deciding official's review within 60 calendar days of the first meeting of the inquiry committee, unless the research integrity officer approves an extension for good cause. If the research integrity officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent will also be notified of the extension. The general counsel will review the report for legal sufficiency.

VII. Federal Oversight

A. Decision to Investigate

If the deciding official decides that an investigation of possible scientific misconduct in PHS- or NSF-funded research will be conducted, the research integrity officer, through the Office of Research, will notify ORI or NSF and will forward a copy of the final inquiry report and these policies and procedures to the respective agency.

B. Decision Not to Investigate

If the deciding official decides not to proceed to an investigation and the inquiry was begun at the request of ORI, NSF, or other funding agency, or if any agency requests a copy, the research integrity officer, through the Office of Research, will send a copy of the final inquiry report and the institutional decision to the appropriate agency. Otherwise, the PHS- or NSF-funded case may be closed without notice to ORI or NSF.

C. Access to Evidence

If either ORI or NSF is performing an oversight review of the university's determination not to proceed to an investigation, the research integrity officer, if so requested, will provide the respective agency with the report and the inquiry file, including, but not limited to, sequestered evidence, analyses, and transcripts of

interviews. The research integrity officer will keep all records secure until the agency makes its final decision on its oversight of the university's inquiry or investigation.

VIII. Referral to Other Agencies

Information obtained during the inquiry regarding allegations other than scientific misconduct involving PHS or NSF funds should be referred to the responsible officials or government agencies. See section III.J.

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

B. Sequestration of the Research Records B.Sequestration of the Research Records

The research integrity officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should 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 a number of reasons, including the institution's 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. See section V.B.

C. Notification of the Respondent

The research integrity officer will notify the respondent as soon as reasonably possible after the determination is made to open an investigation. The notification should include: a copy of the inquiry report; the specific allegations; the presence, source, and implication of PHS or NSF funding; the definition of misconduct; the procedures to be followed in the investigation, including the appointment of the investigation committee and experts; the opportunity of the respondent to be

interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report; the fact that either ORI or NSF may perform an oversight review of the report if that agency funded the research; and an explanation of the respondent's right to request a hearing before the agency's appellate process if there is a finding of misconduct under that agency's definition.

D. Designation of an Official or a Committee to Conduct the Investigation

The research integrity officer is responsible for conducting or designating others to conduct the investigation.

1. Use of an Investigation Committee - In complex cases, the research integrity officer will normally appoint a committee to conduct the investigation, following the procedures set forth in section IX.E. (see below).

2. Use of an Investigation Official - In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the research integrity officer may choose to conduct the investigation directly or designate another qualified individual to do so. In such cases, the investigation official will nevertheless obtain the necessary expert and technical advice to consider properly all scientific or ethical issues. In such a case, the research integrity officer will offer the respondent a chance to comment on this decision; any comments will be recorded as an attachment to the investigation report.

3. Investigation Process - The investigation, whether conducted by a committee or an individual, will follow each procedural step set forth below.

E. Appointment of the Investigation Committee

If an investigation committee is to be appointed, the research integrity official will use the following procedures

1. Committee Membership - Normally the Faculty Senate Committee D, Research and Scholarly Activity will comprise the investigation committee. In general, the investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are believed to be fair and 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. If the Faculty Senate Committee D does not satisfy this standard, or is inappropriate for the purposes of maintaining confidentiality, then the research integrity officer,

in consultation with the president and general counsel, will appoint an investigation committee and the committee chair within 10 calendar days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside Old Dominion University. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The research integrity officer will notify the respondent of the proposed committee membership within five days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the research integrity officer will immediately replace the first challenged member or expert with a qualified substitute, observing the 30-day time limit. In additional written objections, the research integrity officer will determine whether to replace challenged members or experts with qualified substitutes.

2. Experts - Experts may be appointed as noted in section V.F.2 (or carried over from the inquiry) to advise the committee on scientific or other issues.

3. Bias or Conflict of Interest - The research integrity officer will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflict of interest with the respondent, complainant, or the case in question. See section V.F.3.

4. Objection to Committee or Experts by Respondent - The research integrity officer will notify the respondent of the proposed committee membership within five days. If the respondent submits a written objection to any appointed member of the investigation committee or expert based on bias or conflict of interest, the research integrity officer will immediately replace the first challenged member or expert with a qualified substitute and determine whether to replace other members or experts the respondent challenges.

5. Confidentiality - Members of the committee and experts will agree in writing to maintain the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the research integrity officer to have knowledge of the investigation.

F. Charge to the Investigation Committee and the First Meeting

1. Charge to the Committee - The research integrity officer 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 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, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, 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 research integrity officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

The inquiry report will be made available to the investigation committee. However, the report in no way limits the evidence available to the committee for consideration. Inasmuch as any decision of an investigation may conflict with any conclusion of the inquiry, the investigation will be considered a de novo process.

2. The First Meeting - The research integrity officer, with the assistance of the general 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 federal agency funding is involved, the PHS or NSF regulation.

G. Developing an Investigation Plan

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the complainant, respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the investigative report.

H. General Approaches to Conducting the Investigation

During the investigation, the committee will take the following steps.

1. Avoid Bias or Conflict of Interest - All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, complainant, and witnesses.

2. Refer Other Issues - The research integrity officer must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy. See section III.E.3 and III.J.

3. Consult with the Research Integrity Officer and General Counsel - The investigation committee should consult the research integrity officer and general counsel throughout the investigation on compliance with these procedures, PHS or NSF regulations if applicable, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The research integrity officer and general counsel will be present or available throughout the investigation to advise the committee.

I. Reviewing the Evidence

The investigation committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

J. Conducting Interviews

The investigation committee will conform to the following guidelines.

1. Conducting the Interviews - The investigation committee will conduct the interviews as described in section V.I., except that at the investigative stage interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.

2. Preparing for Interviews - The investigation committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

3. Objectivity - The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

4. Transcribing Interviews - Any interview with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

5. Recording Admissions of Misconduct - If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The committee should consult with the general counsel on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. If applicable, the committee may ask the research integrity officer or general counsel to consult with ORI or NSF when deciding whether an admission has adequately addressed all the relevant issues such that the investigation can be considered completed. The investigation should not be closed unless the respondent has been appropriately notified and given an opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the deciding official with recommendations for appropriate institutional actions and, if applicable, to ORI or NSF for review.

K. Committee Deliberations

1. Burden and Standard of Proof - In reaching a conclusion on whether there was misconduct and who committed it, the burden of proof is on the university to support its conclusions and findings by a preponderance of the evidence. See section III.G.

2. Definition of Misconduct

   a. In the case of PHS-funded research, to comply with PHS regulations, the committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific or professional community at the time the actions were committed.

   b. In the case of NSF-funded research, to comply with NSF regulations, the committee will consider whether falsification, fabrication, or

plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific or professional community at the time the actions were committed. In addition, the committee will consider whether there was retaliation against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

c. Notwithstanding subparagraphs a. and b., the committee will always consider the Old Dominion University definition of misconduct (as defined in Section IV.A.4) for appropriate university response in the absence of federal agency funding. Included in this category are cases of possible retaliation for the reporting of misconduct in PHS-funded research. Accordingly, the investigation committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific or professional community at the time the actions were committed. In addition, the committee will consider whether there was retaliation against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

3. Sufficient Evidence - The committee will consider whether there is sufficient evidence of intent such that the university can meet its burden of proving misconduct by a preponderance of the evidence. The committee will also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that misconduct cannot be proven by a preponderance of the evidence.

X. The Investigation Report

A. Elements of the Investigation Report

1. Background - The report will include sufficient background information to ensure a full understanding of the issues. This section should describe the facts leading to the investigation, including a chronology of the research at issue, the persons involved in the alleged misconduct, and the role of the complainant. If PHS or NSF funding is involved, the report should include any associated grant applications or publications and any public health issues. This section should summarize the university's inquiry and investigation processes, including the composition of the committees, the persons interviewed, the evidence secured and reviewed, the policies and procedures used, and any other factors that may have influenced the proceedings. All relevant dates should be included.

Because the PHS definition of scientific misconduct does not include retaliation, information and findings about retaliation may be omitted from the main body of the report submitted to ORI. Information about the allegation of retaliation will be referenced in an appendix to the main report as described in X.A.5.e. and X.A.6.b. Notwithstanding this variation in the definition of misconduct and the attendant variation in reporting requirements, Old Dominion University will always treat retaliation as misconduct for the purposes of internal administrative response.

This requirement does not arise in research not funded by PHS because the Old Dominion University definition of misconduct in scientific research or in other scholarly activity includes retaliation, thereby conforming to the NSF definition.

2. Allegations - The report will list all the allegations raised by the complainant and any additional misconduct issues that arose during the inquiry and investigation stages. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a complainant requesting anonymity is compromised or the identity of the source is irrelevant or unnecessary. In the case of possible retaliation in NSF-funded research, this section would describe both the core misconduct reported and the retaliation that has been alleged.

3. PHS or NSF Support - In the absence of PHS or NSF support, the report will include a brief statement of the sources of research funding, if any. For each allegation of misconduct under the PHS or NSF definition, the report will identify the PHS or NSF support for the research or report at issue.

4. Respondent's Claims - The report should summarize each claim that the respondent raises in his or her defense against the misconduct allegations and cite the source of each claim. Any inconsistencies among the respondent's various claims should be noted. The report should not consider claims that do not address the allegations at issue; allegations of personal bias by the complainant, for example, should not be addressed in the report unless they are relevant to the report's conclusions.

5. Analysis

    a. The report will provide a detailed analysis of the evidence that either supports or does not support a finding of misconduct. This analysis should take into account all the relevant statements, claims, rebuttals, documents, and other evidence related to the case. Any use of expert analysis should be noted.

b. The analysis should be consistent with the appropriate definition of misconduct as noted in section II. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness. It should demonstrate how a consideration of the evidence as a whole led to the report's findings. A finding of misconduct should be supported by a preponderance of the evidence.

c. The report should summarize or quote relevant statements, including rebuttals, made by the complainant, respondent, and other witnesses pertinent to the report's analysis and findings. The report should provide references to the appropriate sources.

d. If the investigation committee determines that the respondent committed fabrication, falsification, or plagiarism, the report should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on prior research findings, research subjects, and the laboratory or project in which the misconduct occurred. If the investigation committee determines that the respondent committed misconduct by seriously deviating from "other commonly accepted practices," the report should thoroughly document the commonly accepted practice of the relevant scientific or professional community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publications, university standards, or relevant professional societies, state and federal regulations, expert opinion, and other sources should be described and cited as the basis for the commonly accepted practice. The serious deviation therefrom should be described in detail, including an analysis of why it is a serious ethical deviation.

e. If the investigation committee determines that the respondent retaliated against a person reporting misconduct or relevant information, that information will be treated differently based on the source of funding. If the research was PHS supported, these findings will be included as an appendix to the report submitted to ORI. The appendix will include the Old Dominion University definition of misconduct and explain why the PHS definition does not apply. If the research was not funded by PHS, but by NSF or other, then the report need not have this appendix, but merely should indicate the extent and seriousness of the retaliation and the surrounding circumstances in the body of the main report.

f. Misconduct does not include honest error or honest differences in interpretations or judgments of data. If the investigation committee

concludes that misconduct occurred, the report should describe the evidence that shows that the respondent acted with intent to commit the misconduct. Specifically, the report should describe any evidence that the respondent knowingly committed the falsification, fabrication, plagiarism, or other conduct that constitutes serious ethical deviation from commonly accepted practices. If the investigation committee concludes that honest error or difference of scientific opinion occurred with respect to any issue, the report should describe the evidence supporting that finding.

g. All significant pieces of evidence should be referenced in the analysis, and copies of the significant evidence should be appended to the report.

6. Findings

a. Issues - The report will concisely state the investigation committee's finding for each identified issue. The final investigation report should make separate findings regarding whether each issue constitutes misconduct, using the appropriate definition of "misconduct." See sections II. and IV.A.2. If the investigation committee finds misconduct on one or more issues, the report should identify the type of misconduct for each issue; i.e., "fabrication," "falsification," "plagiarism," or "other practices that seriously deviate from those that are commonly accepted within the scientific or professional community."

b. Misconduct found under the University's definition but not the PHS definition - The investigation committee may determine that an issue, such as retaliation, that does not constitute misconduct under the PHS definition is, nevertheless, misconduct under the Old Dominion University definition (Section II.K). Any issue that the investigation committee determines to be misconduct under the Old Dominion University definition should be identified as such in an appendix to the report. These findings are not subject to ORI's jurisdiction, if ORI agrees that they do not meet the PHS definition.

7. Old Dominion University Response - Based on its findings, the investigation committee will recommend the administrative actions that it believes the university should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, or other action. These actions will include, where appropriate, a plan to restore the reputation of any innocent respondent or complainant and to protect good faith complainants against retaliation.

The committee may identify any published research reports or professional contributions that should be retracted or corrected based on the finding of misconduct and take steps to assure that journal editors are notified.

8. Summary - The final investigation report should conclude with a detailed and specific summary of the institution's finding for each issue, an overall finding of whether misconduct occurred, and if applicable, the PHS or NSF support for each finding of misconduct under that agency's definition.

B. Standard Format of the Investigation Report

The following outline should be used in preparing the Investigation Report, except when special factors suggest a different approach. The outline should incorporate all of the elements described in section X.A.

1. Overview and Summary of Findings
   * Separate findings for each issue

2. Funding (Jurisdictional Requirement for PHS or NSF Funding)

3. Background
   * Chronology of events
   * Include public health sensitivities

4. List of allegations and other issues identified by the investigation committee

5. Institutional Inquiry: Process and Recommendations

6. Institutional Investigation: Process
   * Committee members
   * Individuals interviewed
   * Evidence sequestered and reviewed

7. Institutional Investigation: Analysis
   For each issue:
   * Finding
   * Background
   * Analysis of all the relevant evidence and specific identification of evidence supporting the finding
   * Effect of Misconduct (e.g., potential harm to research subjects, reliability of data)
   * Summary

8. Conclusions and Recommended Institutional Actions

9. Optional Appendix of X.A.6.b.

10. Attachments

C. Documenting the Investigative File

1. Index of Evidence - The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to: research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

2. Purpose of Documentation - The purpose of the documentation is to substantiate the investigation's findings.

3. Record Retention - After completion of a case and all ensuing related actions, the research integrity officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the research integrity officer or committees. The research integrity officer will keep the file for three years after completion of the case to permit later assessment of the case. NSF, ORI or other authorized DHHS personnel will be given access to the records upon request.

D. Comments on the Draft Report

1. Respondent - The research integrity officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed ten 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 should take into account the respondent's comments in addition to all the other evidence.

2. Complainant - The research integrity officer 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 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. 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 research integrity officer will inform the recipient of the confidentiality under which the draft report is made available and will establish conditions to ensure such confidentiality. For example, the research integrity officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

E. Institutional Review and Decision

Based on a preponderance of the evidence, the deciding official will make the final determination whether to accept the investigation report, its findings, and the recommended actions. If this determination varies from that of the investigation committee, the deciding official will explain in detail the basis for rendering a decision different from that of the investigation committee. In the case of PHS or NSF funding, this letter will be included in the letter transmitting the report to ORI or the NSF inspector general. The deciding official's explanation should be consistent with the appropriate definition of misconduct, the university's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The deciding official may also return the report to the investigation committee with a request for further fact-finding or analysis. In the case of PHS-funded research, the deciding official'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 research integrity officer will notify both the respondent and the complainant in writing. In addition, the deciding official 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 research integrity officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

F. Transmittal of the Final Investigation 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 deciding official, through the research integrity officer.

G. Time Limit for Completing the Investigation Report

The final investigation report will be completed within 120 calendar days of the first meeting of the investigation committee. In the case of PHS or NSF funding, the report will be submitted to ORI or NSF within these 120 calendar days unless the

university submits a written request for extension and the agency grants the extension. All attachments to the final report should be submitted with the report. The research integrity officer should maintain all other evidence and materials for possible agency review.

XI. Institutional Administrative Actions

Old Dominion University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the deciding official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the research integrity officer. The actions may include:

* withdrawal or correction of all pending or published abstracts, papers emanating from the research, and exhibits or displays where misconduct was found.

* removal of the responsible person from the particular project, letter of reprimand, or special monitoring of future work.

* sanctions such as probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.

* restitution of funds as appropriate.

XII. Other Considerations

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

The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible 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, if applicable, the ORI or NSF concurs, after consulting with the respondent, the research integrity officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the research integrity officer 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 actions to restore the respondent's reputation must first be approved by the deciding official.

C. Protection of the Complainant and Others

Regardless of whether a determination of misconduct is made or if an agency concurs, the research integrity officer 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 deciding official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The research integrity officer is responsible for implementing any steps the deciding official approves. The research integrity officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

D. Allegations Not Made in Good Faith

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

E. Interim Administrative Actions

The dean of the affected college and the Office of Research will take appropriate interim administrative actions to protect any federal funds involved and ensure that the purposes of the federal financial assistance are carried out.

XIII. Agency Review of the Investigation Report and Follow-up

A. Purpose of ORI or NSF Review

Funding agencies review the final investigation report, the supporting materials, and the deciding official’s determinations to decide whether the investigation has been

performed in a timely manner and with sufficient objectivity, thoroughness, and competence. Based on its review, the agency may:

1. request additional information;

2. accept all the findings and conclusions of the report;

3. accept all or part of the factual findings of the report and make its own conclusions;

4. request additional investigation;

5. reject the report and conduct its own investigation;

6. impose administrative actions on the respondent beyond those recommended by the institution;

7. refer the case for review of the university's regulatory compliance; or

8. take any other action deemed to be in the public interest and within the agency's authority.

ORI will attempt to complete its review of the institution's report within 180 days of its receipt, except where additional follow-up activities are required, such as an ORI request for additional information or analysis or where further investigation is necessary. NSF will normally assess the accuracy and completeness of an investigation report within 30 days; similarly, NSF will evaluate the procedure, recommend adoption of the findings in whole or in part, or initiate a new investigation.

B. Cooperation with Agency Review

For research they fund, ORI (PHS) and the NSF are authorized to review institutional reports on allegations of misconduct. In reviewing the report, an agency may request additional information or other assistance from the research integrity officer or other university officials. If the university official receiving the ORI or NSF request is unsure how to respond, he or she should consult with the research integrity officer or general counsel. The general counsel may consult with agency counsel prior to advising the university official on how to respond.

C. Request for Additional Documents and Information

The research integrity officer will cooperate with any agency request for additional relevant documents and information by responding to all requests in a timely and

responsive fashion. The research integrity officer may consult with the general counsel for advice as needed.

D. Notification of Agency Determination

1. ORI Concurrence - If ORI concurs with the university's findings, ORI will notify the respondent and appropriate university officials in writing and will send the respondent and appropriate university officials a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of misconduct, the respondent will be notified of his or her opportunity to appeal to the DHHS Departmental Appeals Board (DAB). See 59 *Fed. Reg.* 29809 (1994).

2. ORI Nonconcurrence- If ORI does not concur with the university's findings, ORI will notify the appropriate university official of the basis for that decision. If ORI does not concur with a finding of no misconduct, the university may be requested to conduct a further investigation, either with the same or a different investigation committee, or ORI may conduct its own investigation. In the latter instance, ORI will notify the appropriate individuals of its investigation.

3. NSF Concurrence - If NSF concurs with a university finding of no misconduct, the NSF inspector general will notify the subject of the investigation and the appropriate university personnel. If NSF concurs with a finding of misconduct, in a case in which NSF considers debarment an appropriate disposition, that case will be referred to the debarring official. If NSF concurs in a case in which debarment is not an appropriate disposition, then that case will be referred to the deputy director for a decision on the recommended disposition within 45 days after completion of the investigation; the deputy director may concur, initiate further hearings or investigation, or specify additional actions. An affected individual may appeal the deputy director's decision in writing within 30 days after receiving notification. Otherwise the decision becomes a final administrative action.

4. NSF Nonconcurrence - If NSF does not concur with the university's findings, NSF will notify the appropriate university official of the basis for that decision. If NSF does not concur with a finding of no misconduct, the university may be requested to conduct a further investigation, either with the same or a different investigation committee, or NSF may conduct its own investigation.

E. Cooperation in Appealed Cases

For cases in which ORI concurs with the institution's findings of misconduct under the PHS definition or makes its own finding of misconduct, ORI will request institutional employees to cooperate in presenting ORI findings of misconduct before the DAB if the respondent appeals the findings. Cooperation includes providing evidence, testimony, or any other information needed to assist in the preparation and presentation of ORI's case before the DAB. Institutional employees may consult with the research integrity officer or institutional counsel in responding to ORI's request for cooperation.

XIV. Record Retention

After completion of a case and all ensuing related actions, the research integrity officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the research integrity officer or committees. The research integrity officer will keep the file for at least three years after completion of the case to permit later assessment of the case. Authorized agency personnel will be given access to the records upon request.

APPENDIX

This appendix summarizes the responsibilities assigned to the deciding official and the research integrity officer. The appendix is a review of the duties assigned to these two officials.

Responsibilities of the Deciding Official

- 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 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 the agency requested the inquiry

Responsibilities of the Research Integrity Officer

Receipt of Allegations

- 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
- May conduct the inquiry in appropriate cases
- Appoints the inquiry official or committee, as required
- Replaces the first challenged person with a qualified substitute and determines whether to replace other challenged persons
- Determines whether additional expertise is needed
- Establishes conditions of confidentiality
- Protects against bias or conflicts-of-interest
- Develops the charge
- Provides the inquiry official or committee with advice on appropriate procedures
- 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 deciding official
- Communicates the decision of the deciding official to the inquiry committee, 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 deciding official
- Undertakes reasonable efforts to restore the reputation of cleared respondents
- Undertakes reasonable efforts to protect "good faith" complainants and others who cooperated with the inquiry

Conduct of Investigation

- Notifies the respondent that an investigation will be conducted
- Sequesters additional research records when necessary
- May conduct the investigation in appropriate cases
- Appoints the investigation official or committee
- Replaces the first challenged person and determines whether to replace persons challenged later
- Determines whether additional expertise is needed

- Establishes conditions of confidentiality
- Protects against bias or conflicts-of-interest
- Develops the charge
- Convenes the first meeting of the investigation committee
- Provides the investigation official or committee with advice on appropriate procedures
- Meets ORI or NSF notification requirements, if relevant
- Takes appropriate interim administrative actions
- Seeks advice from federal agencies when an admission of misconduct is made
- Requests an extension if necessary from ORI or NSF and submits progress reports
- Submits plan to terminate an investigation to ORI or NSF
- Provides a draft report to the respondent
- Provides appropriate portions of the draft report to the complainant
- Transmits the final report and comments to the deciding official
- Notifies the respondent and complainant of the institution's findings and actions
- Retains all records of investigation
- Reports "bad faith" allegations to the deciding official
- Undertakes reasonable efforts to restore the reputation of cleared respondents
- Undertakes reasonable efforts to protect "good faith" complainants and others who cooperated with the inquiry

Post-Investigation

- Responds to requests from federal agencies for additional information or assistance during the review process
- Responds to requests from ORI for additional information or assistance during a DAB appeal