# SUNY State College of Optometry

# Policy for Responding to Allegations of Scientific Misconduct


## Office of Graduate Programs and Research

## June 2010

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# I. Introduction[a]

## A. General Policy: Statement of Principles of Appropriate Conduct of Intellectual and Creative Activity

The State University of New York, State College of Optometry as a public institution of higher learning, is committed to promoting the highest quality scholarly activity including research, intellectual and creative activity. In exercising this commitment, the College requires adherence to the highest ethical standards by faculty, administrators, students, staff, and fellows. Professional integrity in the conduct of scholarly activity by all members of the College community is crucial for the functioning of the College.

The College supports established principles and conventions designed to protect the integrity of scholarly activities and expects its members to adhere to the code of ethics that govern professional conduct in their disciplines.

Each member of the College bears responsibility for the integrity of the scholarly activity in which he or she is engaged. Each individual also has the responsibility to promote the highest ethical standards within his or her profession. In collaborative scholarly activity, each principal investigator, author or creator, bears added responsibility for the integrity of the activity as a whole and in its parts. As a guide to those engaged in scholarly activity, and other interested parties, the College recommends the following principles of ethical conduct which incorporate and expand those developed by the Society of Sigma Xi, the honorary research society of North America.[b] This list does not purport to be all inclusive.

o Honesty and integrity in research hold the highest priority.
o Only honest-data are used.
o No data are taken from other sources without proper and clear attribution of source.
o Fabrication, falsification and plagiarism of data are violations of research

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[a] Sections that are based on requirements of the PHS regulations codified at 42 CFR Part 50, Subpart A have endnotes that indicate the applicable section number, e.g. 42 CFR 50.103(d)(1).

[b] Jackson, C.I. and J.W. Prados, American Scientist, Sept/Oct., 1983

integrity.
o Data are obtained by processes that comply with State and Federal requirements affecting specific rules of research conduct.
o All persons named as authors should concur and should have made a definable major contribution to the work reported. Minor contributions should be explicitly acknowledged in the work. Co-authorship should not be acknowledged in the work. Co-authorship should not be conferred or accepted solely as an honor or a reward for providing resources.
o All authors of a manuscript prepared for publication must have confidence in the integrity of the data and should be prepared to take responsibility for the resultant paper's contents in precisely the same measure a they stand to take credit.
o After analysis and publication of research results, data are willingly shared with others.
o The data gathering process or data sources are clearly described or made available, allowing independent replication or source verification.
o In these principles, "Data" is used throughout in an inclusive sense, extending to arguments, bibliographies, and phraseology.

B. Scope

This policy and the associated procedures apply to all individuals at SUNY State College of Optometry engaged in research that is supported by or for which support is requested from PHS. The PHS regulation at 42 CFR Part 50, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at SUNY, State College of Optometry.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of SUNY State College of Optometry and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Associate Dean for Graduate Programs and Research of SUNY State College of Optometry.

## II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. *Complainant* means a person who makes an allegation of scientific misconduct.

C. *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.

D. *Deciding Official* means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

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

F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.[1]

G. *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.[2]

H. *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.

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

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

K. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefor.

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

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

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

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

P. *Scientific misconduct or misconduct in science* means 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.[3]

## III. Rights and Responsibilities

### A. Research Integrity Officer

The Associate Dean for Graduate Programs and Research will serve as the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

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

The Research Integrity Officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.[4]

### B. Complainant

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

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

C. Respondent

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

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.[5]

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

## IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with SUNY State College of Optometry should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Research Integrity Officer at (212) 780-5111 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant

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

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also the institution will protect the privacy of those who report misconduct in good faith[6] to the maximum extent possible. For example, if the complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.[7]

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.[8]

Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

D. Cooperation with Inquiries and Investigations

Institutional 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.

E. Preliminary Assessment of Allegations

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

## 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, involves PHS support, and falls under the PHS definition of scientific 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 scientific 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. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science and involves PHS funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are

immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

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

D. 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 scientific misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether scientific 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 institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

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

## 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 PHS 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 or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

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 portions of the draft inquiry report that address the complainant's role and opinions in the investigation.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the

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 inquiry report and record.[9] 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 scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 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 inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting,[10] 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.[11] The respondent also will be notified of the extension.

## VII. Conducting the Investigation

A. Purpose of the Investigation

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

B. Sequestration of the Research Records

The 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 any 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.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation.[12] These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. 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 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The 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 scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the 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.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation

plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.[13]

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.[14] Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations.[15] Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.[16]

## VIII. The Investigation Report

A. Elements of the Investigation Report

The final report submitted to ORI must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.[17]

B. 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 10 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. Institutional Counsel

The draft investigation report will be transmitted to the institutional 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 may establish reasonable 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.

C. 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 institutional 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 institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of scientific misconduct, the institution'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. 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.

D. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the 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.

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation,[18] with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI.[19]

## IX. Requirements for Reporting to ORI

A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins.[20] 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 PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.[21] ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[22] Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.[23]

C. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.[24]

D. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.[25]

E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

1. there is an immediate health hazard involved;[26]

2. there is an immediate need to protect Federal funds or equipment;[27]

3. 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;[28]

4. it is probable that the alleged incident is going to be reported publicly;[29] or

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

6. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.[30]

## X. Institutional Administrative Actions

SUNY, State College of Optometry will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.[31]

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 and papers emanating from the research where scientific misconduct was found.

- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

- restitution of funds as appropriate.

## XI. Other Considerations

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

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

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

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, 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 scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others[32]

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the 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 scientific 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

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.[33]

## XII. 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. ORI or other authorized DHHS personnel will be given access to the records upon request.[34]

# SUNY State College of Optometry

# Procedures for Responding to Allegations of Scientific Misconduct

## Office of Graduate Programs and Research

## July 1995

# Table of Contents

## I. Introduction

The purpose of these procedures is to provide advice to institutional officials on the methods and principles for assessing allegations and conducting inquiries and investigations related to possible scientific misconduct in research proposed to or supported by the U.S. Public Health Service. These procedures also address requirements for reporting scientific misconduct investigations to PHS, adopting institutional actions in response to findings of scientific misconduct, and cooperating with the Office of Research Integrity in its review of institutional actions and reports. These procedures are intended to guide institutional officials responsible for assessing allegations, conducting inquiries and investigations, and reporting the results to ORI. 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 SUNY State College of Optometry's Policy for Dealing with Scientific Misconduct.

## II. Definitions[35]

A. *Allegation* means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. *Complainant* means a person who makes an allegation of scientific misconduct.

C. *Deciding Official* means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

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

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

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

G. *Institutional counsel* means legal counsel who represents the institution during the scientific 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 institutional counsel does not represent the respondent, the complainant, or any other person participating during the inquiry, investigation, or any follow-up action, except the institutional officials responsible for managing or conducting the institutional scientific misconduct process as part of their official duties.

H. *Investigation* means the formal examination and evaluation of all relevant facts to determine if scientific misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

I. *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.

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

K. *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."

L. *PHS support* means Public Health Service grants, contracts, or cooperative agreements, or applications therefor.

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

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

O. *Respondent* means the person against whom an allegation of scientific 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.

P. *Retaliation*[36] 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 scientific misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

Q. *Scientific misconduct or misconduct in science* means 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.

## III. General Procedures and Principles

A. Responsibility to Report Misconduct

Institutional employees who receive or learn of an allegation of scientific misconduct will immediately report the allegation to the Research Integrity Officer for appropriate action. The Research Integrity Officer will promptly engage in an assessment of the allegation to determine whether it falls within the definition of scientific misconduct, involves PHS support, and provides sufficient information to proceed with an inquiry.

B. Protecting the Complainant[37]

Institutional employees who receive or learn of an allegation of scientific 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 the position and reputation of the complainant and other individuals who cooperate with the institution against retaliation. Employees will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

C. Protecting the Respondent[38]

Institutional employees who receive or learn of an allegation of scientific misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 C.F.R. Part 50, Subpart A, and these procedures are followed. 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[39]

Institutional employees who make, receive, or learn of an allegation of scientific 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 to ensure the confidentiality of such information.

E. Responding to Allegations

In responding to allegations of scientific 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.[40]

2. Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation.[41]

3. Immediate notification is provided to ORI if:[42]

    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 coinvestigators and associates, if any;

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

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

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

4. 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.[43]

F. Employee Cooperation[44]

Institutional 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 in its conduct of inquiries and investigations, its oversight of institutional inquiries and investigations, and any follow up actions.

G. Evidentiary Standards[45]

The following evidentiary standards apply to findings of scientific misconduct made under the PHS regulation.

1. Burden of Proof

The burden of proof for making a finding of scientific misconduct is on the institution. **[Note: If ORI adopts the institutional finding of scientific misconduct or makes an ORI finding, the burden of proof is on ORI for purposes of its finding and administrative actions.]**

2. Standard of Proof

Any institutional or ORI finding of scientific 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 scientific misconduct.

H. Completion of Process

The Research Integrity Officer is responsible for ensuring that the inquiry/investigation process and all other steps required by this instruction and the PHS regulation are completed even in those cases where the respondent leaves the institution after allegations are made.

I. Early Termination[46]

If the institution plans to terminate an inquiry or investigation prior to completion of all the steps required by the PHS regulation, the Research Integrity Officer will notify ORI of the planned termination and the reasons therefore. ORI will 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 or Federal office for action. Issues requiring referral are described below.

1. HHS Criminal Violations[47]

Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General, HHS-OIG Hot line, P.O. Box 17303, Baltimore, MD 21203-7303, telephone (800) 368-5779. 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.

2. Violation of Human and Animal Subject Regulations

Potential violation of human or animal subject regulations should be referred to the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20892-7507, telephone (301) 496-7005.

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) 443-2390.

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, Building 31, Room 1B05, Bethesda, MD 20892, telephone (301) 496-1361.

   b. For all other PHS Agencies--PHS Office of Grants and Contracts, 5600 Fishers Lane, Room 17A39, Rockville, MD 20857, telephone (301) 443-6630.

If there are any questions regarding the proper referral of non-scientific misconduct issues, the Research Integrity Officer may call the ORI Division of Research Investigations at (301) 443-5330 to obtain advice.

K. Requirements for Reporting to ORI

1. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins.[48] 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 PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.[49] ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[50] Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

2. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.[51]

3. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.[52]

4. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.[53]

5. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

    a. there is an immediate health hazard involved;[54]

    b. there is an immediate need to protect Federal funds or equipment;[55]

    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;[56]

    d. it is probable that the alleged incident is going to be reported publicly;[57] or

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

    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.[58]

## IV. Preliminary Assessment of Allegations

### A. Allegation Assessment

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

1. PHS Support

   Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support. If the allegation does not involve PHS support, it should be handled under the institution's own definition of scientific misconduct and procedures **[if applicable]** without regard to the PHS regulation at 42 C.F.R. Part 50, Subpart A.

2. PHS Definition

   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 institutional counsel or ORI on whether the allegation falls within the PHS definition of scientific misconduct.

3. 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 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 scientific misconduct inquiry is warranted, if the allegation involves PHS support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation should be referred to the appropriate PHS or DHHS office. See section III-J.

## V. Conducting the Inquiry[59]

A. Initiation and Purpose of the Inquiry[60]

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific 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 scientific 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 President, President's Council, Department Chairpersons, Chair of IRB and/or IACUC, other relevant officials, institutional counsel, the respondent, and ORI (if the request to open the inquiry originated from ORI);

3. appoint and charge the inquiry committee; and

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

The Research Integrity Officer or institutional counsel may consult with ORI 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 grants and cooperative agreements are the property of the institution, and employees cannot interfere with the institution's right of access to them. Under contracts, certain research records may belong to PHS, but the institution will be provided access to contract records in the custody of the institution 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.N 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 institutional 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, a copy of each sequestered record will be provided to the individual from whom the record is taken if requested.

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 an institutional 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 institutional 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 scientific misconduct; identify the PHS funding involved; 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 or each investigator on a questioned grant application. The Research Integrity Officer will consult with the institutional counsel on the proper 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.E.

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 scientific 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 institutional officials as appropriate, will appoint the committee and committee chair within 10 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 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 the institution.

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 scientific 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 physician/patient 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 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Research Integrity Officer will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality

Members of the committee and experts will agree in writing to observe the confidentiality of the proceeding 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 institutional 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 scientific misconduct to warrant an investigation, as required by the PHS regulation. The purpose is not to determine whether scientific 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 institutional 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. 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.

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 judgement 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, the Research Integrity Officer or institutional counsel may seek advice from ORI 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 ORI for review. If the respondent admits to the misconduct, the Research Integrity Officer will advise the committee to consult with the institutional counsel immediately, with the option of seeking advice from ORI 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 institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

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 scientific interpretations. These questions should be reserved for private discussions among the inquiry committee members and expert consultants.

## VI. The Inquiry Report[61]

### 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 PHS 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. Institutional 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[62]

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

#### 2. Receipt of Comments

Within 7 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.[63] Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification[64]

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 scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 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 inquiry committee will complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting,[65] 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.

## VII. ORI Oversight[66]

A. Decision to Investigate

If the Deciding Official decides that an investigation will be conducted, the Research Integrity Officer [or other designated official, if applicable] will notify ORI and will forward a copy of the final inquiry report and the institution's policies and procedures for conducting investigations to ORI.

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 or if ORI requests a copy, the Research Integrity Officer will send a copy of the final inquiry report and the institutional decision to ORI. Otherwise, the case may be closed without notice to ORI.

C. Access to Evidence

If ORI is performing an oversight review of the institution's determination not to proceed to an investigation, the Research Integrity Officer, if so requested, will provide ORI 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 ORI makes its final decision on its oversight of the institutional inquiry or investigation.

## VIII. Referral to Other Agencies

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

## IX. Conducting the Investigation[67]

A. Purpose of the Investigation

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

B. Sequestration of the Research Records

The 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 any 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 sources of PHS funding; the definition of scientific 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 ORI will perform an oversight review of the report regarding PHS issues; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS 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 of three or more persons to conduct the investigation, following the procedures set forth in section IX.E.

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 issues.

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

   The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint the investigation committee and the committee chair within 10 days of the notification to the respondent or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation.[68] These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

2. Experts

   Experts may be appointed as noted in section V.E.2-4 (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.E.3.

4. Objection to Committee or Experts by Respondent

   The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 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 determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality

   Members of the committee and experts will agree in writing to observe 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 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 scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the

respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the 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.

2. The First Meeting

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

   The Research Integrity Officer and institutional counsel should be consulted throughout the investigation on compliance with these procedures and PHS regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The Research Integrity Officer and institutional 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.G., 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

   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 institutional 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. The committee may ask the Research Integrity Officer or institutional counsel to consult with ORI 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 then to ORI for review. If the respondent admits to the misconduct, the institution will advise the committee to consult with the institutional counsel immediately, with the option of seeking advice from ORI as needed.

K. Committee Deliberations

1. Burden and Standard of Proof

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

2. Definition of Scientific Misconduct

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 community at the time the actions were committed.

3. Sufficient Evidence

The committee will consider whether there is sufficient evidence of intent such that the institution 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 scientific misconduct cannot be proven by a preponderance of the evidence.

## X. The Investigation Report[69]

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 institutional investigation, including a chronology of the research at issue,

the persons involved in the alleged misconduct, the role of the complainant, any associated grant applications or publications, and any public health issues. This section should summarize the institution'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.

2. Allegations

   The report will list all the allegations raised by the complainant and any additional scientific 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.

3. PHS Support

   For each allegation of scientific misconduct under the PHS definition, the report will identify the PHS 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 scientific 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 scientific 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 definition of scientific 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 scientific 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 scientific misconduct by seriously deviating from "other commonly accepted practices," the report should thoroughly document the commonly accepted practice of the relevant scientific community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publications, standards of the institution 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 deviation.

e. Scientific misconduct does not include honest error or honest differences in interpretations or judgments of data. If the investigation committee concludes that scientific 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 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.

f. 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. PHS 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 or not each issue constitutes scientific misconduct, using the PHS definition of "misconduct in science." See sections II and IV.A.2. If the investigation committee finds scientific 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 community."

b. Misconduct under the Institution's Policies

The investigation committee may determine that an issue that does not constitute scientific misconduct under the PHS definition is, nevertheless, scientific misconduct under the institution's own definition. Any issue that the investigation committee determines to be scientific misconduct solely under the institution's own definition should be identified as such. These findings are not subject to ORI's jurisdiction, if ORI agrees that they do not meet the PHS definition.

7. Institutional Actions

Based on its findings, the investigation committee should recommend the administrative actions that it believes the institution should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, etc. These actions should include, where appropriate, a plan to restore the reputation of any innocent respondent or complainant and to protect good faith complainants against retaliation. The institution should also identify any published research reports that should be retracted or corrected based on

the finding of misconduct and take steps to assure the 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 scientific misconduct occurred, and the PHS support for each finding of scientific misconduct under the PHS 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. PHS 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. 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. ORI or other authorized DHHS personnel will be given access to the records upon request.[70]

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 7 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report 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. Institutional Counsel

The draft investigation report will be transmitted to the institutional 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 may establish reasonable 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 institutional 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 institution's letter transmitting the report to ORI. The Deciding Official's

explanation should be consistent with the PHS definition of scientific misconduct, the institution'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. 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 to ORI

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 submitted to ORI within 120 days of the first meeting of the investigation committee, unless the institution requests a written request for extension and ORI 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 ORI review.

## XI. Institutional Administrative Actions

SUNY State College of Optometry will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.[71]

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 and papers emanating from the research where scientific misconduct was found.

- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

- restitution of funds as appropriate.

## XII. Other Considerations

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

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

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

B. Restoration of the Respondent's Reputation[72]

If the institution finds no misconduct and ORI 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 scientific misconduct was previously publicized,

or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others[73]

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the 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 scientific 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

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.[74]

## XIII. ORI Review of the Investigation Report and Follow-up[75]

A. Purpose of ORI Review

ORI reviews 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, ORI may

1. request additional information from the institution;

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 by the institution;

5. reject the report and conduct its own investigation;

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

7. refer the case to the Division of Policy and Education, ORI, for a review of the institution's regulatory compliance;[76] or

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

B. Cooperation with ORI Review[77]

ORI is authorized by statute and PHS regulations to review institutional reports on allegations of scientific misconduct. In reviewing an institution's report, ORI may request additional information or other assistance from the Research Integrity Officer or other institutional officials. If the institutional official receiving the ORI request is unsure how to respond, he or she should consult with the Research Integrity Officer or institutional counsel. Institutional counsel may consult with ORI counsel prior to advising the institutional official on how to respond.

C. Request for Additional Documents and Information

The Research Integrity Officer will cooperate with any ORI request for additional documents and information by responding to all requests in a timely and responsive fashion. The Research Integrity Officer may consult with institutional counsel for

advice as needed.

D. Notification of ORI Determination

1. ORI Concurrence

If ORI concurs with the institution's findings, ORI will notify the respondent and appropriate institutional officials in writing and will send the respondent and appropriate institutional official a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of scientific 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 institution's findings, ORI will notify the appropriate institutional official of the basis for that decision. If ORI does not concur with a finding of no misconduct, the institution 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.

E. Cooperation in Appealed Cases[78]

For cases in which ORI concurs with the institution's findings of scientific misconduct under the PHS definition or makes its own finding of scientific 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.

## IX. Record Retention[79]

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 of 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. ORI or other authorized DHHS personnel will be given access to the records upon request.

# Appendix

# Appendix

This appendix summarizes the responsibilities assigned to the institutional Deciding Official and the institutional Research Integrity Officer in the model policy and model procedures. The appendix is provided to help institutions quickly review the duties assigned to these two officials in these models so that an individual institution can determine if these assignments are appropriate and desirable.

## Responsibilities of the Deciding Official

- Determines whether an investigation is warranted
- Determines whether to accept 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
- Determines institutional administrative actions against "bad faith" complainants
- Informs ORI that an investigation is not warranted if ORI requested the inquiry

## Responsibilities of the Research Integrity Officer

### Receipt of Allegations

- Receives allegations of scientific misconduct
- Receives allegations of retaliation
- Receives reports of "bad faith" allegations
- Receives reports of violations of PHS regulation

### 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, ORI that an

inquiry is underway
- Sequesters research records
- May conduct the inquiry in appropriate cases
- Appoints the inquiry official or committee
- Determines whether to replace 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 notification requirements
- Takes appropriate interim administrative actions
- Seeks advice from ORI when an admission occurs
- 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 appropriate parties
- Notifies ORI if an investigation will be conducted
- Provides the final report and inquiry file to ORI upon request
- 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 other 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
- Determines whether to replace challenged persons
- 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 notification requirements

- Takes appropriate interim administrative actions
- Seeks advice from ORI when an admission occurs
- Requests an extension if necessary from ORI and submits progress reports
- Submits plan to terminate an investigation to ORI
- 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 ORI for additional information or assistance during the review process
- Responds to requests from ORI for additional information or assistance during a DAB appeal

# PHS Regulation
# 42 CFR Part 50, Subpart A

Appendix B

# Endnotes

# Endnotes

42 CFR 50.102.

42 CFR 50.102.

42 CFR 50.102.

42 CFR 50.103(d)(12).

42 CFR 50.103(d)(13).

42 CFR 50.103(d)(2).

42 CFR 50.103(d)(13).

42 CFR 50.103(d)(3).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(8).

42 CFR 50.103(d)(7).

42 CFR 50.103(d)(7).

42 CFR 50.103(d)(7).

42 CFR 50.103(d)(7).

42 CFR 50.104(a)(4); 42 CFR 50.103(d)(15).

42 CFR 50.104(a)(2).

42 CFR 50.104(a)(2).

42 CFR 50.104(a)(1).

42 CFR 50.104(a)(1).

42 CFR 50.103(d)(15).

42 CFR 50.104(a)(3).

42 CFR 50.104(a)(5).

42 CFR 50.104(a)(3).

42 CFR 50.104(b)(1).

42 CFR 50.104(b)(2).

42 CFR 50.104(b)(3).

42 CFR 50.104(b)(4).

42 CFR 50.104(b)(5).

42 CFR 50.103(d)(14).

Id.

42 CFR 50.103(d)(11).

42 CFR 50.103(d)(10).

Some of the definitions in this section are based on the Public Health Service regulations. 42 CFR 50.102.

42 CFR 50.103(d)(13); See also, 42 USC 289b(e).

Id.

42 CFR 50.103(d)(3) and (13) and 50.104(a)(2).

42 CFR 50.103(d)(2) and (3).

42 CFR 50.104(a)(6).

42 CFR 50.103(d)(9).

42 CFR 50.103(d)(5) and 50.104(b)(1)-(5).

42 CFR 50.103(d)(11).

42 CFR 50.103(c)(3) and (4) and 50.104(a)(6).

Section XI of the Hearing Procedures for Scientific Misconduct, 59 Fed. Reg. 29809, 29811, June 9, 1994; 45 CFR 76.313(c)(1) and (2).

42 CFR 50.104(a)(3).

42 CFR 50.104(b)(5).

42 CFR 50.104(a)(1).

42 CFR 50.104(a)(1).

42 CFR 50.103(d)(15).

42 CFR 50.104(a)(3).

42 CFR 50.104(a)(5).

42 CFR 50.104(a)(3).

42 CFR 50.104(b)(1).

42 CFR 50.104(b)(2).

42 CFR 50.104(b)(3).

42 CFR 50.104(b)(4).

42 CFR 50.104(b)(5).

42 CFR 50.103(d).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(1) and (3).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(4) and (7).

42 CFR 50.103(d)(1).

42 CFR 50.103(d)(6) and 42 CFR 50.103(d)(10).

42 CFR 50.103(d) and 50.104.

42 CFR 50.103(d)(8)

42 CFR 50.104.

42 CFR 50.103(d)(10).

42 CFR 50.103(d)(14).

42 CFR 50.103(d)(13).

Id.

42 CFR 50.103(d)(11).

Id.

42 CFR 50.105.

42 CFR 50.104(a)(6); 42 CFR 50.103(c)(4).

42 CFR 50.103(d)(4).

Id.