

APA Procedures for Responding
To Allegations of Scientific Misconduct

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I. Introduction

The purpose of these procedures is to provide advice to APA 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 APA 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.

II. Definitions¹

- A. *Allegation* means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.
- B. *Deciding Official* means the APA official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.
- C. *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.
- D. *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.
- E. *Inquiry* means information-gathering and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.
- F. *Institutional counsel* means legal counsel who represents the APA 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 whistleblower, 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

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misconduct process as part of their official duties.

- G. *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.
- 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 U.S. Department of Health and Human Services.
- 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 Public Health Service grants, contracts, or cooperative agreements, or applications therefor.
- L. *Research Integrity Officer* means the APA official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing any 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 who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

- O. *Retaliation*² 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.
- 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.
- Q. *Whistleblower* means a person who makes an allegation of scientific misconduct

III. General Procedures and Principles

A. Responsibility to Report Misconduct

APA members or 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 Whistleblower³

APA members or employees who receive or learn of an allegation of scientific misconduct will treat the whistleblower 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 whistleblower and other individuals who cooperate with the institution against retaliation. APA members or employees will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

C. Protecting the Respondent⁴

APA members or 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

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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. Confidentiality⁵

APA members or 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 whistleblower, 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.⁶
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.⁷
3. Immediate notification is provided to ORI if⁸:
 - 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;

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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.⁹

F. Employee Cooperation¹⁰

APA members or 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, APA members or 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 Standards¹¹

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.

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 Termination¹²

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 Violations¹³

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 violations of human subject regulations should be referred to the Office of Human Research Protections, Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, Rockville, MD 20892-7507. Phone: 301-496-7005. Email: ohrp@osophs.dhhs.gov.

Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare, National Institutes of Health, 6705 Rockledge Drive, RKL1, Suite 1050, MSC 7982, Bethesda, MD 20892-7982, Phone: 301-402-5913.

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, HFC-230 TWBK 715, Rockville, MD 20857, telephone

(301) 827-0420.

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.¹⁴ 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.¹⁵ ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.¹⁶ 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.¹⁷
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

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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.¹⁸

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.¹⁹
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;²⁰
 - b. there is an immediate need to protect Federal funds or equipment;²¹
 - 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;²²
 - d. it is probable that the alleged incident is going to be reported publicly;²³ 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.²⁴

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

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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.

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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 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 whistleblower, 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 Inquiry²⁵

A. Initiation and Purpose of the Inquiry²⁶

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, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is **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 APA Board of Directors, 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 at the University or University where the allegation occurred 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 at the University or Universities where the allegation occurred 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

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whistleblowers. 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 whistleblower against

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retaliation and the need to maintain the whistleblower'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.

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 APA.

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 APA.

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, whistleblower, 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 whistleblower;
- b. has been a coauthor on a publication with the respondent or whistleblower;

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- c. has been a collaborator or coinvestigator with the respondent or whistleblower;
- d. has been a party to a scientific controversy with the respondent or whistleblower;
- e. has a supervisory or mentor relationship with the respondent or whistleblower;
- f. has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or whistleblower; 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

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respondent, whistleblower, 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, whistleblower, 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, whistleblower, 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, whistleblower, 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 whistleblower, 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 Whistleblower

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

10. Interviewing the Respondent

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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.

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 Report²⁷

A. Elements of the Inquiry Report

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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 Whistleblower²⁸

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with those portions of the draft report that address the whistleblower'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 whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final report and record.²⁹ Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification³⁰

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.

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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 whistleblower 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,³¹ 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 Oversight³²

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 [or other designated official] 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 Investigation³³

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

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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.

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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 Officer 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.³⁴ 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

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members of the committee and the experts have no bias or personal or professional conflict of interest with the respondent, whistleblower, 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, whistleblower, 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, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

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

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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.

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

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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

A. Outline for an Investigation Report

The following annotated outline may prove useful in preparing the Investigation Report required by the Office of Research Integrity (42 C.F.R. Part 50, Subpart A), except when special factors suggest a different approach.

1. Background

Include sufficient background information to ensure a full understanding of the issues that concern the PHS under its definition of scientific misconduct. This section should detail the facts leading to the institutional inquiry, including a description of the research at issue, the persons involved in the alleged misconduct, the role of the whistleblower, and any associated public health issues. All relevant dates should be included.

2. Allegations

List all the allegations of scientific misconduct raised by the whistleblower and any additional scientific misconduct allegations that arose during the inquiry and investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a whistleblower requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

3. PHS Support

For each allegation of scientific misconduct under the PHS definition, identify the PHS support for the research or report (*e.g.*, publication) at issue or the application containing the falsification/fabrication or plagiarism.

4. Institutional Inquiry: Process and Recommendations

Summarize the inquiry process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the

institution's policies and procedures), and any other factors that may have influenced the proceedings.

5. Institutional Investigation: Process

Summarize the investigation process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

6. Institutional Investigation: Analysis

For each allegation:

Background

Describe the particular matter (*e.g.*, experiment or component of a clinical protocol) in which the alleged misconduct occurred and why and how the issue came to be under investigation.

Analysis

The analysis should take into account all the relevant statements, claims (*e.g.*, a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (*e.g.*, laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).

Any use of additional expert analysis should be noted (forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures).

Summarize or quote relevant statements, including rebuttals, made by the whistleblower, respondent, and other pertinent witnesses and reference/cite the appropriate sources.

Summarize each argument that the respondent raised in his or her defense against the scientific misconduct allegation and cite the

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source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

The analysis should be consistent with the terms of PHS definition of scientific misconduct. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Describe any evidence that shows that the respondent acted with intent, that is, any evidence that the respondent knowingly engaged in the alleged falsification, fabrication, plagiarism, or other conduct that constitutes a serious deviation from commonly accepted practices.

Similarly, describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

Conclusions

a. Findings of Misconduct or No Misconduct

Concisely state the investigation committee's finding for each identified issue. The investigation report should make separate findings as to whether or not each issue constitutes scientific misconduct, using the PHS definition.

A finding of scientific misconduct should be supported by a preponderance of the evidence. Institutions may have their own standard of proof under their scientific misconduct policies and procedures, one that may be higher than preponderance of the evidence. In such cases, ORI has requested institutions to reexamine the evidence and report to ORI what their conclusions would have been under a preponderance of the evidence standard.

If the investigation committee finds scientific misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community). The report should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings,

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publications, 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, indicating why the alleged act was a serious deviation.

b. Misconduct under the Institution's Policies

The investigation committee may determine that an action that does not constitute scientific misconduct under the PHS definition is, nevertheless, scientific misconduct under the institution's own definition (*e.g.*, clinical protocol deviations or other violations of human subjects protection; documented animal welfare concerns; substandard data management practices; deficient mentoring of trainees). 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 or jurisdictional basis.

7. Recommended Institutional Actions

Based on its findings, the investigation committee should recommend 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, termination, etc. The institution should also identify any published research reports or other sources of scientific information (such as data bases) that should be retracted or corrected and take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

Attachments

Copies of all significant documentary evidence that is referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and whistleblower responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments."

It is useful to identify allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc., on a copy of the page or section of the questioned document (*e.g.*, a page from a research notebook). A side-by-side comparison with the actual data or material that is alleged to have been plagiarized is helpful.

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 report should incorporate all of the elements described in section X.A.

1. Background
 - Chronology of events
 - Include public health issues
2. Allegations
3. PHS Support or Application(s) (by allegation)
4. Institutional Inquiry: Process and Recommendations
 - Composition of committee
 - Individuals interviewed
 - Evidence sequestered and reviewed

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5. Institutional Investigation: Process
 - Composition of committee
 - Individuals interviewed
 - Evidence sequestered and reviewed

6. Institutional Investigation: Analysis
 - For each allegation:
 - Background
 - Analysis of all the relevant evidence and specific identification of evidence supporting the finding
 - Conclusion: scientific misconduct or no scientific misconduct
 - Effect of misconduct (*e.g.*, potential harm to research subjects, reliability of data, publications that need to be corrected or retracted, etc.)

7. Recommended Institutional Actions

8. 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

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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.³⁵

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 14 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. Whistleblower

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

3. Institutional Counsel

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

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, 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

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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 whistleblower 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 whistleblower'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

The Ambulatory Pediatric Association will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.³⁶

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:

- a. withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.
- b. removal of the responsible person from the particular project, or special monitoring of future work;
- c. restitution of funds as appropriate.

XII. Other Considerations

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

The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible 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 Reputation³⁷

If the APA 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 Whistleblower and Others³⁸

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. 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 whistleblower.

D. Allegations Not Made in Good Faith

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

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.³⁹

XIII. ORI Review of the Investigation Report and Follow-up⁴⁰

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:

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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 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,⁴¹ 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 Review⁴²

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 Cases⁴³

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 Retention⁴⁴

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

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authorized DHHS personnel will be given access to the records upon request.

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1. Some of the definitions in this section are based on the Public Health Service regulations. 42 C.F.R. ' 50.102.
 2. 42 C.F.R. ' 50.103(d)(13); See also, 42 U.S.C. ' 289b(e).
 3. Id.
 4. 42 C.F.R. " 50.103(d)(3) and (13) and ' 50.104(a)(2).
 5. 42 C.F.R. " 50.103(d)(2) and (3).
 6. 42 C.F.R. ' 50.104(a)(6).
 7. 42 C.F.R. ' 50.103(d)(9).
 8. 42 C.F.R. ' 50.103(d)(5) and ' 50.104(b)(1)-(5).
 9. 42 C.F.R. 50.103(d)(11).
 10. 42 C.F.R. 50.103(c)(3) and (4) and 50.104(a)(6).
 11. Section XI of the Hearing Procedures for Scientific Misconduct, 59 Fed. Reg. 29809, 29811, June 9, 1994; 45 C.F.R. " 76.313(c)(1) and (2).
 12. 42 C.F.R. ' 50.104(a)(3).
 13. 42 C.F.R. ' 50.104(b)(5).
 14. 42 C.F.R. ' 50.104(a)(1).
 15. 42 C.F.R. ' 50.104(a)(1).
 16. 42 C.F.R. ' 50.103(d)(15).

17. 42 C.F.R. ' 50.104(a)(3).
18. 42 C.F.R. ' 50.104(a)(5).
19. 42 C.F.R. ' 50.104(a)(3).

20. 42 C.F.R. ' 50.104(b)(1).
21. 42 C.F.R. ' 50.104(b)(2).
22. 42 C.F.R. ' 50.104(b)(3).
23. 42 C.F.R. ' 50.104(b)(4).
24. 42 C.F.R. ' 50.104(b)(5).
25. 42 C.F.R. ' 50.103(d).
26. 42 C.F.R. ' 50.103(d)(1).
27. 42 C.F.R. ' 50.103(d)(1).
28. 42 C.F.R. " 50.103(d)(1) and (3).
29. 42 C.F.R. ' 50.103(d)(1).
30. 42 C.F.R. " 50.103(d)(4) and (7).
31. 42 C.F.R. ' 50.103(d)(1).
32. 42 C.F.R. ' 50.103(d)(6) and 42 C.F.R. ' 50.103(d)(10).
33. 42 C.F.R. ' 50.103(d) and ' 50.104.
34. 42 C.F.R. ' 50.103(d)(8)
35. 42 C.F.R. ' 50.103(d)(10).
36. 42 C.F.R. 50.103(d)(14).
37. 42 C.F.R. ' 50.103(d)(13).
38. 42 C.F.R. ' 50.103(d)(13).

- 39. 42 C.F.R. ' 50.103(d)(11).
- 40. 42 C.F.R. ' 50.103(d)(11).
- 41. 42 C.F.R. ' 50.105.

- 42. 42 C.F.R. ' 50.104(a)(6); 42 C.F.R. ' 50.103(c)(4).
- 43. 42 C.F.R. ' 50.103(d)(4).
- 44. 42 C.F.R. ' 50.103(d)(4).