

**MANUAL OF PROCEDURES FOR RESPONDING
TO ALLEGATIONS OF RESEARCH MISCONDUCT**

**Office of Grants and Sponsored Research
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I. Introduction

This procedural manual addresses the federal requirements (42 CFR Part 93) for reporting research misconduct investigations and adopting institutional actions in response to findings of research misconduct. The procedures described in this manual do not create any right or benefit, substantive or procedural, or enforceable by law by any party against The College of New Jersey (“TCNJ” or “the College”), its agencies, officers, or employees. Students are to follow the Academic Integrity Policy.

A. General Policy

Conduct of Research

1. Each member of the College community has the responsibility to ensure that scholarly and scientific research is conducted in accordance with the highest standards of academic integrity. Specifically, those who conduct research or monitor the research of others must strive to ensure that the research:
 - Follows accepted standards concerning evidence and justification applicable to research of that kind;
 - Avoids all forms of fraud, deceit, and dishonesty; and
 - Adheres to accepted scholarly standards regarding proper citation of others' work, and recognizes and acknowledges the intellectual contributions of all members of the College community, including the contributions of their colleagues and students.
2. All research must comply with applicable College, state, and federal policies and regulations as well as professional guidelines commonly accepted within a specific discipline.
3. In the case of applied research¹, care must be taken to ensure that conflicts of interest between the impartial and objective search for knowledge and the prospect of personal profit or gain do not occur.

B. Scope

This statement of policy and procedures is intended to carry out the College’s responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.* This

¹ Applied Research – research designed to solve practical problems of the modern world, rather than to acquire knowledge. Differs from Basic Research

Basic Research – fundamental research that is driven by a scientist's curiosity or interest that answers a scientific question. This type of research acquires and/or expands knowledge

document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with the College;¹ and

- (1) Has conducted PHS and/or NSF supported² biomedical or behavioral research, research training, or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, and/or
- (2) Has submitted applications or proposals for PHS and/or NSF support for biomedical or behavioral research, research training, or activities related to that research or research training, and
- (3) Has fabricated, falsified, and/or plagiarized research records produced in the course of PHS and/or NSF supported or other externally sponsored research, research training, or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.²

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the College or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

II. Definitions³

- A. *Allegation* - Any written or oral statement or other indication of possible research misconduct made to a College official.
- B. *Complainant* - A person who makes an allegation of research misconduct.
- C. *Deciding Official* - The College of New Jersey official who makes final determinations on allegations of research misconduct and any responsive College actions.
- D. *Employee* - Any person paid by, under the control of, or affiliated with the College, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.
- E. *Fabrication*⁴ – Recording and/or reporting made up data and/or results.

² Also applies to research funded by corporate and private sources

- F. *Falsification*⁵ – The misrepresentation of the research record by changing or omitting data and/or manipulating research materials, equipment, and/or processes.
- G. *Good faith allegation* - An allegation made with the honest belief that research 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.
- H. *Inquiry* - Information-gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
- I. *Institutional counsel* - Legal counsel who represents the College during the research 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 College officials responsible for managing or conducting the institutional research misconduct process as part of their official duties.
- J. *Investigation* - The formal examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.
- K. *ORI* - The Office of Research Integrity, an office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.
- L. *PHS* - The U.S. Public Health Service, an operating component of the U.S. Department of Health and Human Services.
- M. *PHS regulation* - The Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research 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."
- N. *PHS support* - Public Health Service grants, contracts, or cooperative agreements, or applications therefore.
- O. *Plagiarism*⁶ – The appropriation of another person's ideas, processes, results or words without appropriate credit.
- P. *Research Integrity Officer* - The College official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing any inquiries and investigations.

- Q. *Research Misconduct*⁷ – The fabrication, falsification, or plagiarism in proposing or performing research or reporting research results. Honest error and/or differences in opinion are not research misconduct.
- R. *Research record* - 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 research 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.
- S. *Respondent* - The person against whom an allegation of research 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.
- T. *Retaliation*⁸ - Any action that adversely affects the employment or other status of an individual that is taken by the College or an employee because the individual has, in good faith, made an allegation of research misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.
- U. *Research misconduct or misconduct in science* - 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.
- V. *Sponsored Research Compliance Committee* - The committee responsible for ensuring adherence to research compliance unit policies and procedures and addressing issues related to Conflict of Interests, Financial Conflict of Interests, Responsible Conduct in Research, Research Misconduct, Intellectual Property, Data Ownership, Technology Transfer, and Export Controls. Issues related to IRB/HIPAA and IACUC are addressed in separate committees. An ad hoc committee is formed when issues related to BioSafety, DNA and Hazardous Materials arise.

III. Rights and Responsibilities

A. Research Integrity Officer

The Provost/ Vice President for Academic Affairs will appoint the Research Integrity Officer (RIO) who will have primary responsibility for implementation of the College's policies and

procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult or assign someone to consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify or assign someone to notify ORI of special circumstances, in accordance with this policy;
- Sequester or assign someone to sequester research data and evidence pertinent to the allegation of research misconduct in accordance with this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify or assign someone to notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with this policy;
- Inform or assign someone to inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- If an inquiry and/or investigation committee is needed, coordinate with the Sponsored Research Compliance Committee (SRC), assign a chair, and ensure that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence. Identify and add to the SRC internal and/or third-party subject matter experts if necessary.
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against

them by respondents or other College employees;

- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions;
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant *should* be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant *must* be interviewed during an investigation, and be given the transcript or recording of the interview for correction.⁹

On the basis of case-by-case determinations, the College may provide to the complainant for comment:

- (1) Relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and
- (2) The draft investigation report or relevant portions of it.

Comments on the draft investigation report must be submitted within 30 days of the date on which the complainant received the draft report. The College must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify or assign someone to notify the respondent in writing at the time of or before beginning an inquiry;¹⁰
- An opportunity to comment on the inquiry report and have his/her comments attached

to the report;¹¹

- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the College's policies and procedures on research misconduct;¹²
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the College decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;¹³
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;¹⁴
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;¹⁵ and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the College and addressed in the final report.¹⁶

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other College officials, the Deciding Official may terminate the College's review of an allegation that has been admitted, if the College's acceptance of the admission and any proposed settlement is approved by ORI.¹⁷

D. Deciding Official ("DO")

The DO will receive the inquiry report and after consulting with the RIO and/or other College officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI by the RIO, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the

inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.¹⁸

The DO will receive the investigation report and, after consulting with the RIO and/or other College officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All College employees will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the complaint.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

College employees will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. College employees, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall, as required by 42 CFR § 93.108 : (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

The RIO should use written confidentiality agreements or other mechanisms to ensure that the

recipient does not make any further disclosure of identifying information. The RIO may want to provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise be retaliated against.

D. Protecting complainants, witnesses, and committee members

College employees may not retaliate in any way against complainants, witnesses, or committee members. College employees should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.¹⁹

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents 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.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other College officials and ORI, take appropriate interim action to protect against any such threat.²⁰ Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;

- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.²¹

G. Responding to Allegations

In responding to allegations of research misconduct, the RIO and any other College 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.²²
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.²³
3. Interim administrative actions are taken, as appropriate, to protect Federal funds and the public health, and to ensure that the purposes of the Federal financial assistance are carried out.²⁴

H. Employee Cooperation²⁵

College employees will cooperate with the RIO and other College officials in the review of allegations and the conduct of inquiries and investigations. Employees have a responsibility to provide relevant evidence to the RIO or other College officials on misconduct allegations. Further, employees will cooperate with the appropriate agencies in their conduct of inquiries and investigations, and follow up thereto.

I. Evidentiary Standards²⁶

The following evidentiary standards apply to findings of research misconduct.

1. Burden of Proof

The burden of proof for making a finding of research misconduct is on the College, unless the appropriate agency adopts the College's finding of research misconduct or makes its own finding, in which case, the burden of proof is on the agency for purposes of its finding and administrative actions.

2. Standard of Proof

Any finding of research 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 research misconduct.

J. Completion of Process

The RIO is responsible for ensuring that the inquiry/investigation process and all other steps required by this instruction and, as applicable, the PHS regulation are completed, even in those cases where the respondent leaves the College after allegations are made.

K. Early Termination²⁷

If the College plans to terminate an inquiry or investigation prior to completion of all the steps as described in this document, and the research involves PHS support, the RIO will notify ORI of the planned termination and the reasons therefore.

L. Referral of Non-Research misconduct Issues

When the College's review of the allegation identifies non-research misconduct issues, the RIO should refer these matters to the proper institutional or federal office for action. Issues requiring referral are described below.

HHS Criminal Violations²⁸

Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General (“OIG”), 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 research 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 the OIG.

If there are any questions regarding the proper referral of non-research misconduct issues, the RIO may call the ORI Division of Research Investigations at (301) 443-5330 for guidance.

M. Requirements for Reporting to ORI

1. If the College decides to initiate an investigation, and the research involves PHS support, the decision must be reported in writing to the ORI Director on or before the date the investigation begins.²⁹

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 research misconduct, and
- the PHS applications or grant number(s) involved.³⁰

ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.³¹ Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

2. If the College plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.³²
3. If the College determines that it will not be able to complete the investigation in 120 days, the RIO will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.³³
4. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the RIO 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 support, the College cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.³⁴

V. Preliminary Assessment of Allegations

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103.³⁵ An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.

1. PHS Support

Allegations involving research supported by PHS and/or NSF-funded grants, contracts, or cooperative agreements, or applications for PHS/NSF funding connote PHS/NSF support.

2. 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 RIO may consult with the institutional counsel or ORI, if the research involves PHS/NSF or other sponsored research support.

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 research misconduct inquiry is warranted, if the allegation involves PHS/NSF or other sponsored 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.

VI. Conducting the Inquiry³⁶

A. Initiation and Purpose of the Inquiry³⁷

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.³⁸

B. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester

• Sections based on 42 CFR Part 93 have endnotes indicating the applicable section.

them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.³⁹ The RIO may consult with ORI for advice and assistance in this regard.

C. Sequestration of the Research Records

1. Immediate Sequestration

If the relevant research records have not been obtained at the assessment stage, the RIO 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 grants and cooperative agreements are the property of the College, and employees cannot interfere with the College's right of access to them.

3. Original Records

The documents and materials to be sequestered will include all of 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.R of this document.

4. Sequestration of the Records from the Respondent

The RIO 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 RIO 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 RIO 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 RIO will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of a College 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 RIO 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 research 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 College to cooperate; describe the College's policy on protecting the complainant against retaliation (in process and to be approved). 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 RIO 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 RIO is responsible for conducting or designating others to conduct the inquiry.

1. Use of an Inquiry Committee

In complex cases, the RIO will work with three or more persons from the Sponsored Research Committee (SRC) to conduct the inquiry, following the procedures set forth in sections VI.G-I.

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 RIO 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 following procedures are recommended:

1. Committee Membership

The RIO, in consultation with other College officials as appropriate, will facilitate a meeting with the SRC within 10 days of the initiation of the inquiry. The inquiry committee should consist of at least three individuals from the SRC 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. If necessary, the RIO and/or SRC may invite a subject matter expert from outside of the SRC to be a part of the inquiry committee.

2. Experts

The RIO, 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 College.

3. Bias or Conflict of Interest

The RIO 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 RIO 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 co-investigator 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 RIO 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 RIO 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 RIO to have knowledge of the inquiry.

6. Provision of Assistance

The RIO, in consultation with Human Resources, 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 RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;

- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines:
 - (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and,
 - (2) the allegation may have substance, based on the committee’s review during the inquiry;
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

H. General Recommended 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 RIO 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.

I. General Recommended 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, 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

Interviewees 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 judgment occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

11. Recording Admissions

If the respondent admits to the misconduct, the respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is a sufficient basis to proceed directly to an investigation. However, the admission may not be a sufficient basis for closing a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made, the RIO may seek advice from the appropriate agency 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 the appropriate agency for review.

12. Committee Deliberations

The SRC will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether there is sufficient evidence of possible research 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.

J. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.⁴⁰

VII. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information:

- (1) the name and position of the respondent;
- (2) a description of the allegations of research misconduct;
- (3) the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;
- (4) the basis for recommending or not recommending that the allegations warrant an investigation;
- (5) any comments on the draft report by the respondent or complainant.⁴¹

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the SRC. The inquiry report may also include:

- the names and titles of the committee members and experts who conducted the inquiry;
- a summary of the inquiry process used;
- a list of the research records reviewed; summaries of any interviews; and
- whether any other actions should be taken if an investigation is not recommended.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within approximately 10 days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.⁴²

The College may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment

within 10 days. A confidentiality agreement should be a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

C. Institutional Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO and/or the DO's designee, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to ORI

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's and/or the DO's designee's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision.

The RIO must provide the following information to ORI upon request:

- (1) the institutional policies and procedures under which the inquiry was conducted;
- (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- (3) the charges to be considered in the investigation.⁴³

3. Documentation of Decision Not to Investigate

If the DO and/or the DO's designee, decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of decision. These documents must be provided to ORI or other authorized HHS personnel upon request.

VIII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO and/or the DO's designee, that an investigation is warranted.⁴⁴ The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the

initial allegations. This is particularly important where the alleged research 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. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Sequestration of the Research Records

The RIO 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 College'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. Notification to the Respondent

On or before the date on which the investigation begins, the RIO must:

- (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and
- (2) notify the respondent in writing of the allegations to be investigated.

The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.⁴⁵

Recommended notification information includes:

- a copy of the inquiry report;
- the specific allegations;
- the sources of PHS funding;
- the definition of research 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/NSF issues if appropriate; and,
- if PHS/NSF support is involved, 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 as defined in Section II.V of this document.

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

The RIO is responsible for conducting or designating others to conduct the investigation.

1. Use of an Investigation Committee

In complex cases, the RIO will normally appoint three or more persons from the SRC to conduct the investigation.

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 RIO 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.

- E. Appointment of the Investigation Committee

If the SRC is to be appointed, the following procedures are recommended:

1. Committee Membership

The RIO, in consultation with other College officials as appropriate, will appoint the SRC and the committee chair within 10 days of the notification to the respondent or as soon thereafter as practicable. The SRC 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.⁴⁶ These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the College. Individuals appointed to the investigation committee may also have served on the inquiry committee.

2. Experts

Experts may be appointed as noted in section to advise the committee on scientific or other issues.

3. Bias or Conflict of Interest

The RIO 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.

4. Objection to Committee or Experts by Respondent

The RIO 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 RIO 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 RIO to have knowledge of the investigation.

F. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of misconduct and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that:
 - (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion);
 - (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and
 - (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly.

- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

2. First Meeting

The RIO 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 this statement of policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

G. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;⁴⁷
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;⁴⁸
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation;⁴⁹ and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.⁵⁰

H. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI Division of Research Investigations at (301) 443-5330 or <https://ori.hhs.gov/handling-misconduct> a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress

reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.⁵¹

I. General Approaches to Conducting the Investigation

During the investigation, it is recommended that the committee 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 RIO 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.

3. Consult with the Research Integrity Officer and institutional counsel

The RIO, Office of Grants and Sponsored Research, 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 RIO, Office of Grants and Sponsored Research, and institutional counsel will be present or available throughout the investigation to advise the committee.

J. 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.

K. Conducting Interviews

The investigation committee should conform to the following guidelines:

1. Conducting the Interviews

The investigation committee will conduct the interviews. 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, 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. In the case of PHS/NSF or other external sponsor funded research, the committee may ask the RIO 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.

L. Committee Deliberations

1. Burden and Standard of Proof for PHS Funded Research

In reaching a conclusion on whether there was research misconduct and who committed it, the burden of proof is on the College to support its conclusions and findings by a

preponderance of the evidence.

2. Determining whether Research misconduct Occurred

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 College 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 research misconduct cannot be proven by a preponderance of the evidence.

IX. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent [*Option: The respondent's c.v. or resume may be included as part of the identification*];
- Describes and documents the PHS support, including, for example, the numbers of grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation.⁵² Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable

explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS/NSF or other sponsor support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies⁵³ and/or other external sponsors.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.⁵⁴

2. Complainant

On a case-by-case basis, the institution may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If the institution chooses this option, the complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be included and considered in the final report. See 42 CFR §§ 93.312(b) and 93.313(g).

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, [*Option: and complainant*] the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO and/or the DO's designee, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO and/or the DO's designee will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO and/or the DO's designee may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. After informing ORI, the DO and/or the DO's designee will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Suggested Outline for an Investigation Report

The following annotated outline may prove useful in preparing the Investigation Report required by the Office of Research Integrity for PHS/NSF funded research (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 underlie the allegation of research 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 complainant, and any associated public health issues. All relevant dates should be included.

2. Allegations

List all of the allegations of research misconduct raised by the complainant and any additional research 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 complainant 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. Supported Projects

For each allegation of research misconduct, identify the source and amount of 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 College'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 College'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 of 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 complainant, 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 research misconduct allegation and cite the source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

The analysis should be consistent with the terms of the definition of research misconduct in Section II.V of this document. 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

- 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 research misconduct, using the definition in Section II.V.
- A finding of research misconduct should be supported by a preponderance of the evidence.
- If the investigation committee finds research 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, publications, research subjects, and the laboratory or project in which the misconduct occurred.
- If the investigation committee determines that the respondent committed research 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 College 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 from these should be described in detail, indicating why the alleged act was a serious deviation, whether misconduct does 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 College 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 College should also identify any published research reports or other sources of scientific information (such as databases) that should be retracted or corrected and take steps to ensure that appropriate officials who can affect 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 (e.g. relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and complainant 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.

E. Standard Format of the Investigation Report

The following outline may be used in preparing the Investigation Report, except when special factors suggest a different approach.

1. Background
 - Chronology of events
 - Include public health issues
2. Allegations
3. Support or Application(s) for Support (by allegation)
4. Institutional Inquiry: Process and Recommendations
 - Composition of committee
 - Individuals interviewed
 - Evidence sequestered and reviewed
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: research misconduct or no research 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

F. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to ORI: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the College accepts the findings of the investigation report; (3) a statement of whether the College found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.⁵⁵

G. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request, “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.⁵⁶ The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.⁵⁷

X. Completion of Cases; Reporting Premature Closures to ORI

1. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.⁵⁸

XI. Institutional Administrative Actions

If the DO and/or the DO’s designee determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research 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 to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

XII. Other Considerations

A. Termination 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 research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the College receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.⁵⁹ Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in

good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.⁶⁰ The DO and/or the DO's designee will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO and/or the DO's designee approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO and/or the DO's designee determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

NOTES:

1. 42 CFR § 93.214
2. 42 CFR § 93.102
3. Some of the definitions in this section are based on the Public Health Service regulations. 42 C.F.R. ' 50.102.
4. From 45 CFR part 689 definitions
5. 45 CFR 689 definitions
6. 45 CFR 689 definitions
7. 45 CFR 689 definitions
8. 42 C.F.R. ' 50.103(d)(13); See also, 42 U.S.C. ' 289b(e).
9. 42 CFR § 93.310(g)
10. 42 CFR §§ 93.304(c), 93.307(b)
11. 42 CFR §§ 93.304(e), 93.307(f)
12. 42 CFR § 308(a)
13. 42 CFR § 310(c)
14. 42 CFR § 310(g)
15. 42 CFR § 310(g)
16. 42 CFR §§ 93.304(f), 93.312(a)
17. 42 CFR § 93.316
18. 42 CFR § 93.309(c)
19. 42 CFR § 93.304(k)
20. 42 CFR § 93.304(h)
21. 42 CFR § 93.318
22. 42 C.F.R. ' 50.104(a)(6).
23. 42 C.F.R. ' 50.103(d)(9).
24. 42 C.F.R. 50.103(d)(11).
25. 42 C.F.R. 50.103(c)(3) and (4) and 50.104(a)(6).
26. Section XI of the Hearing Procedures for research misconduct, 59 Fed. Reg. 29809, 29811, June 9, 1994; 45 C.F.R. " 76.313(c)(1) and (2).
27. 42 C.F.R. ' 50.104(a)(3).
28. 42 C.F.R. ' 50.104(b)(5).
29. 42 C.F.R. ' 50.104(a)(1).
30. 42 C.F.R. ' 50.104(a)(1).
31. 42 C.F.R. ' 50.103(d)(15).
32. 42 C.F.R. ' 50.104(a)(3).
33. 42 C.F.R. ' 50.104(a)(5).
34. 42 C.F.R. ' 50.104(a)(3).
35. 42 CFR § 93.307(a)
36. 42 C.F.R. ' 50.103(d).
37. 42 C.F.R. ' 50.103(d)(1).
38. 42 CFR § 93.307(c)
39. 42 CFR §§ 93.305, 93.307(b)
40. 42 CFR § 93.307(g)
41. 42 CFR § 93.309(a)
42. 42 CFR § 93.308(a)
43. 42 CFR § 93.309(a) and (b)
44. 42 CFR § 93.310(a)
45. 42 CFR § 93.310(b) and (c)
46. 42 C.F.R. ' 50.103(d)(8)
47. 42 CFR § 93.310(e)
48. 42 CFR § 93.310(f)
49. 42 CFR § 93.310(g)
50. 42 CFR § 93.310(h)
51. 42 CFR § 93.311
52. 42 CFR § 93.313
53. 42 CFR § 93.313(f)
54. 42 CFR §§ 93.312(a), 93.313(g)
55. 42 CFR § 93.315
56. 42 CFR § 93.317(b)
57. 42 CFR §§ 93.300(g), 93.403(b) and (d)
58. 42 CFR § 93.316(a)
59. 42 CFR § 93.304(k)
60. 42 CFR § 93.304(l)