Responding to Allegations of Research Misconduct

General Policies and Principles

Statement of Policy

The University of Houston (UH) expects all of its investigators and research teams to adhere to the highest standards of conduct when pursuing, conducting, and reporting research.

- Any form of misconduct is contrary to the principles upon which the University was founded and adversely affects the reputation of the University and its faculty.
- Research misconduct violates not only the trust of agencies, foundations, and other entities that sponsor research at the University, but also that of the public and subjects that might participate in the research.

Research Misconduct Definition

As defined by the Department of Health and Human Services (DHHS) Office of Research Integrity (ORI) and the National Science Foundation (NSF), research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results¹.

- Fabrication: making up data or results and recording or reporting them
- Falsification: manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
- **Plagiarism:** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit²

Research misconduct does not include honest error or differences of opinion.

Applicability

This policy applies to all UH faculty staff, and students, as well as any person who, at the time of the alleged research misconduct was:

¹ 42 CFR 93.214 and 45 CFR 689.1

² DHHS ORI Newsletter, Vol. 15, No. 4, September 2007, page 4: ORI generally pursues plagiarism allegations when, for example, wholesale copying of language and data has been used to produce crucial portions of a grant application such as the preliminary results. However, when reuse of data and language involves former or current collaborators, ORI does not consider this to be plagiarism, but an outcome of the joint development of ideas, data, or language where it frequently is impossible to objectively sort out who was responsible for what."

- Employed by,
- An agent of, or
- Affiliated by contract or agreement with the University of Houston³

The Research Integrity Officer and/or designee will determine the policies and guidelines applicable to the alleged research misconduct and will apply UH policy and the sponsoring agency requirements accordingly:

- Public Health Service (PHS) research requirements contained in 42 CFR 93
- National Science Foundation (NSF) described in Section 930 of the NSF Grant Policy Manual
- Department of Defense (DoD) described in the Instruction 3210.7
- All other funding sources the terms of the funding source guidelines as well as UH policy
- Unfunded research UH policy

This policy does not apply to authorship or collaboration disputes, which are to be addressed under current UH grievance policy and procedures:

Faculty: <u>Faculty Handbook</u>Staff: MAPP 02.04.01

• Students: College-specific policies

Time Limitations on Alleged Research Misconduct

- For PHS funded research In most cases, this policy does not apply to alleged research misconduct that occurred more than six years before the allegation was received by UH or PHS. There are, however, three exceptions under 42 CFR 93.105(b)⁴.
- For NSF research⁵ There are no time limitations. This policy applies to all research, including proposals submitted to NSF in all fields of science, engineering, mathematics and education and results from such proposals, regardless of the date of alleged misconduct.
- For all other research There are time limitations. Unless stated otherwise in funding source guidelines, this policy does not apply to alleged research misconduct that occurred more than six years before the allegation was received by UH.

^{3 42} CFR 93 214

⁴ 42 CFR 93.105(b) (1) **Subsequent use exception.** The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized. (2) **Health or safety of the public exception**. If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. (3) "**Grandfather" exception**. If HHS or an institution received the allegation of research misconduct before the effective date of this part.

⁵ For NSF Research – in addition to these definitions, prior to April 17th, 2002, *Misconduct* also includes: Fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

Research Activities Covered under this Policy

PHS6:

- Biomedical or behavioral research
- Research training
- Activities related to the research or research training (such as the operation of tissue and data banks and the dissemination of research information)
- Applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training
- Plagiarism of research records produced in the course of PHS-supported research, research training or activities related to that research or research training. Note: This includes any research:
 - o Proposed, performed, reviewed, reported
 - Records 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)

NSF7:

 Any research, including proposals submitted to NSF in all fields of science, engineering, mathematics, education, and the results from such proposals.

DoD8:

 All basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, physical sciences, social sciences, statistics, and research involving human subjects or animals regardless of the funding appropriation used to support it. [insert footnote below]

Funded from other sources or not funded:

- Biomedical or behavioral research
- Activities related to the research or research training (such as the operation of tissue and data banks and the dissemination of research information)
- Applications or proposals for funding support for biomedical or behavioral research
- Plagiarism of research records

Roles and Responsibilities

• **Deciding Official (DO):** the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official shall have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. The Deciding Official is the President of the

^{6 42} CFR 93.102

⁷ 45 CFR 689.1(4)

⁸ DoDI 3210.07, É2.1.8

University of Houston. The President has delegated the DO responsibilities, including sanctioning authority, to the Provost.

- **Research Integrity Officer (RIO):** the institutional official, designated by the President, who is responsible for:
 - Assessing allegations of research misconduct to determine if they fall within the definition of research misconduct and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified;
 - Overseeing inquires and investigations, including the appointment of inquiry and investigation committees;
 - o Providing resources necessary to carry out inquiries and allegations; and
 - Other responsibilities described in this policy

The RIO is the Associate Vice President for Research and Technology Transfer.

- **Complainant:** a person who in good faith makes an allegation of research misconduct.
- **Respondent:** the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Responsibility to Report Misconduct

All UH personnel 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 might include discussing it anonymously and/or hypothetically.

Research misconduct may also be reported anonymously using the <u>UH Fraud and Non-Compliance Hotline</u>, however this may limit the extent to which a case may be pursued if the information provided lacks the requisite detail.

If the circumstances described by the individual fail to meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

Cooperation with Research Misconduct Proceedings

UH personnel:

- Will cooperate with the RIO, other institutional officials, and appointed committees in the review of allegations and the conduct of inquiries and investigations
- Have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

Confidentiality

To maintain confidentiality of the misconduct proceeding, the RIO shall⁹:

- 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
- 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
- Use written confidentiality agreements or other mechanisms to ensure that the recipient makes no further disclosure of identifying information

Protecting Complainants, Witnesses, and Committee Members

UH personnel may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses, or committee members to the RIO, who shall review the matter with the DO 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 retaliation is directed.

Protecting the Respondent

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR 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 whose role is to advise, as opposed to represent, the respondent.

Being named as a respondent in a research misconduct proceeding does not prevent a respondent from enrolling or continuing their enrollment in or attending classes at the university.

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 made¹⁰.

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

-

^{9 42} CFR 93.108

^{10 42} CFR 93.304(k)

- Publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized
- Expunging all reference to the research misconduct allegation from the respondent's personnel file

Interim Administrative Actions and Notifying Oversight Agencies

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
- The integrity of the research process

In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, or NSF Office of Inspector General (OIG) or DOD as applicable, take appropriate interim action to protect against any such threat¹¹.

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 or NSF OIG or DOD as applicable 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 or NSF 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 might be necessary to safeguard evidence and protect the rights of those involved
- The research community or public should be informed¹²

Sequestration of Research Records

At the time of or before an inquiry (and at the time of or before investigation, if not sequestered for the inquiry), the RIO must take all reasonable and practical steps to:

6

¹¹⁴² CFR 93.304(h) and 45 CFR 689.4(a)(3)

^{12 42} CFR 93.318 and 45 CFR 689.4(c)

- Obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding
- Inventory the records and evidence and sequester them in a secure manner. **Exception**: When 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 instruments¹³

The need for additional sequestration of records for the investigation might occur for any number of reasons, including the Institution's decision to investigate additional allegations not considered during the inquiry stage, and/or identification of records during the inquiry process that had not been previously secured¹⁴.

The RIO may consult with ORI for advice and assistance in this regard.

<u>Termination or Resignation Prior to Completing Inquiry/Investigation</u>

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
- Limit any of the institution's responsibilities under 42 CFR 93 or 45 CFR 689.4

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct:

- The assessment of the allegation will proceed
- The inquiry and investigation will proceed, 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
- Note in the report the respondent's failure to cooperate and its effect on the evidence

Admission of Misconduct

A finding of misconduct based on the admission by the respondent¹⁵ may only be made by the committee conducting the misconduct proceeding and confirmed by the DO when:

The respondent has been notified of the allegations and any findings;

¹³ 42 CFR 93.305 and 42 CFR 93.307(b)

¹⁴ 42 CFR 93.310(d)

¹⁵ ORI "Handling Misconduct - Inquiry Issues" item 20.

- The respondent has:
 - o Responded to these allegations and findings; or
 - o Waived this opportunity
- The admission is written or transcribed;
- The admission contains language such as "I falsified results" or "I admit to research misconduct;" and
- Sufficient evidence supports the admission.

Conducting the Assessment and Inquiry

Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will assess the allegation to determine whether the allegation:

- Is sufficiently credible and specific so that potential evidence of research misconduct might be identified
- Falls within the definition of research misconduct

The RIO will determine if the allegation falls within the jurisdiction of 42 CFR 93.102(b), 45 CFR 689, or other funding source guidelines.

During the assessment, the RIO need not interview the complainant, respondent, or any other witnesses, or gather any data beyond that submitted with the initial allegation, except as necessary to determine the above criteria.

A written summary of allegations meeting the above criteria and falling under this policy will be provided to the respondent. The full/original concern will be not be relayed verbatim due to the Institution's necessity to protect individuals voicing such concerns in good faith.

The assessment period will be brief, preferably conducted within 2-3 weeks. Any allegation meeting the bulleted criteria above will necessitate an inquiry. In the event that the allegation is found to lack sufficient merit to warrant an inquiry, the RIO will notify both the respondent and complainant of this finding within one week of this determination.

If the RIO determines that an inquiry is not warranted, sufficiently detailed documentation of the determination and items considered will be maintained according to record retention procedures outlined in this procedure.

Initiation and Purpose of the Inquiry

If the RIO determines that all criteria for an inquiry are met, he or she will initiate the inquiry process by appointing an inquiry committee. Each committee is selected on an ad hoc basis and will include at least one member of the faculty senate. UH faculty selected for the committee will be tenured. The Deciding Official (DO)/DO's designee and the Provost of the University will be notified of the initiation of the inquiry and will be provided the opportunity to comment on the specific membership of the inquiry committee.

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.¹⁶

The RIO/designee will prepare a written charge for the inquiry committee that:

.

¹⁶ 42 CFR 93.307(c)

- 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:
 - There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, and
 - 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 applicable federal/funding agency requirements

The date of the RIO's charge to the Chair of the inquiry committee will be considered the initiation of the inquiry.

Notice to Respondent

At the time of or before beginning an inquiry, the RIO/designee 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.

First Meeting of the Inquiry Committee

At the committee's first meeting, the RIO/designee 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, including how to access additional expertise as needed
- Seek disclosure of any unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry
- Answer any questions raised by the committee

The RIO will be present or available throughout the inquiry to advise the committee as needed.

Inquiry Process

The inquiry committee will normally:

- Interview the complainant, the respondent, and key witnesses, as well as examine relevant research records and materials
- Evaluate the evidence, including the testimony obtained during the inquiry

After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this procedure and 42 CFR 93.307(d).

The scope of the inquiry is not required to, and does not normally include:

- Deciding whether misconduct definitely occurred
- Determining definitely who committed the research misconduct
- Conducting exhaustive interviews and analyses

However, if a legally-sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. ¹⁷ If PHS-funded, the institution shall promptly consult with ORI to determine the next steps that should be taken

Time for Completion of Inquiry

Within 60 calendar days of initiation of the inquiry¹⁸ (notification of the committee chair by the RIO/designee), the following must be completed:

- The inquiry, including preparation of the final inquiry report
- The decision of the inquiry committee on whether an investigation is warranted

The RIO may extend the time for completion if circumstances clearly warrant a longer period.

PHS¹⁹:

• If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

NSF²⁰:

• If completion of an inquiry is delayed, but the institution wishes NSF deferral of independent inquiry to continue, NSF might require submission of periodic status reports

Elements of the Inquiry Report

A written inquiry report must be prepared and provided to the RIO that includes the following information²¹:

- The name and position of the respondent
- A description of the allegations of research misconduct
- PHS/NSF support, including for example:
 - Grant numbers
 - o Grant applications

¹⁷ ORI "Handling Misconduct - Inquiry Issues" item 20

¹⁸90 days for NSF research; 45 CFR 689.4(b)(1)

¹⁹ 42 CFR 93.307(g)

²⁰ 45 CFR 689.4 (b)(1)

²¹ 42 CFR 93.309 (a)

- Contracts and publications listing PHS support
- The basis for recommending or not recommending that the allegations warrant an investigation

Notification to Respondent and Opportunity to Comment

The RIO/designee shall notify the respondent whether the inquiry found an investigation to be warranted. This notification will be made within the time constraints of the Inquiry process (see "Time for Completion of Inquiry" section, above), and ideally within one week. The notification will include a copy of:

- The draft inquiry report or relevant portions of the report
- The institution's policies/procedures on research misconduct, with reference to applicable federal regulations based on the agency funding the research

The respondent is offered an opportunity to comment within 10 calendar days. Based on the comments from the respondent, the committee may revise the draft report as appropriate and prepare it in final form. Any comments that are submitted by the respondent will be attached to the final inquiry report.

Institutional Decision and Notification

The inquiry is completed when the committee determines, after opportunity for comment by the respondent and consultation with the RIO, whether or not an investigation is warranted.

The RIO will transmit the final inquiry report and the determination of the inquiry committee to the DO/DO's designee and Provost at the time of or before the investigation is initiated.

Notification to ORI/NSF

Within 30 calendar days of the inquiry committee's decision that an investigation is warranted, the RIO²²:

- Provides ORI or NSF OIG with the written decision and a copy of the final inquiry report
- Notifies additional institutional officials who need to know of the decision to investigate
- Upon request from ORI, must provide:
 - o Institutional policies and procedures under which the inquiry was conducted
 - Research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents
 - Charges to be considered in the investigation
- Inquiry reports are provided to funding agencies based on agency requirements and unless specifically requested by the funding agency, are limited to those cases in which the inquiry determines that an investigation is warranted. Inquiry reports for unfunded research are not reported externally.

. .

²² 42 CFR 93.309(a) and (b)

Documentation of Decision Not to Investigate

If the inquiry committee decides that an investigation is not warranted, the RIO:

- Secures and maintains (for 7 years after the termination of the inquiry) sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted
- Provides these documents upon request from ORI or other authorized HHS personnel

Conducting the Investigation

Initiation and Purpose of the Investigation

The investigation must begin (first investigation committee meeting) within 30 calendar days after the determination by the inquiry committee that an investigation is warranted²³

The purpose of the investigation is to:

- Develop a factual record by exploring the allegations in detail
- Examine the evidence in depth, leading to recommended findings on whether research misconduct has been committed:
 - o By whom
 - o 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
- Potential harm to human subjects or the general public, or
- If it affects research that forms the basis for:
 - Public policy
 - o Clinical practice
 - Public health practice

Under 42 CFR 93.313 and 45 CFR 689.4(b)(5), the findings of the investigation must be set forth in an investigation report.

Notifying ORI/OIG and the Respondent

On or before the date on which the investigation begins, the RIO must notify²⁴:

²⁴ 42 CFR 93.310(b) and (c)

²³ 42 CFR 93.310(a)

- the ORI Director (or NSF OIG as applicable) of the decision to begin the investigation and provide ORI a copy of the inquiry report
- the respondent in writing of the allegations to be investigated.
 - the RIO/designee 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.

The Investigation Committee

The committee charged with the inquiry will proceed with the investigation upon the determination that an investigation is warranted.

The committee Chair, in consultation with the RIO, the DO/DO's designee, and the Provost of the University, will reassess membership to assure that the committee consists of individuals:

- Who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation
- With the appropriate scientific expertise to:
 - o Evaluate the evidence and issues related to the allegation
 - o Interview the respondent and complainant
 - Conduct the investigation

The RIO may appoint committee members from outside the institution when necessary to secure additional expertise or to avoid conflicts of interest.

Charge to the Investigation Committee

The RIO/designee will prepare a written charge for the investigation 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 the Investigation process
- 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
 - o The type and extent of misconduct, if any
 - Who was responsible for any misconduct
- Informs the committee that in order to determine that the respondent committed research misconduct, it must find by a preponderance of the evidence that:
 - Research misconduct, as defined in this policy, occurred (the respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion)
 - The research misconduct is a significant departure from accepted practices of the relevant research community, and

- The respondent committed the research misconduct intentionally, knowingly, or recklessly
- Informs the investigation committee that they are responsible for preparing or directing the preparation of a written investigation report that meets the requirements of this policy and applicable federal/funding agency requirements.

First Investigation Meeting

At the committee's first meeting, the RIO/designee will:

- Review the following with the investigation committee:
 - The charge
 - Inquiry report
 - Prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan
- Seek disclosure of any unresolved personal, professional, or financial conflicts of interest with those involved with the investigation
- Determine how to access additional expertise as needed
- Provide the investigation committee with a copy of this policy, and 42 CFR 93 or 45 CFR 689

The RIO will be present or available throughout the investigation to advise the committee as needed.

Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented, including examination of all research records and evidence relevant to reaching a decision on the merits of each allegation²⁵
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical²⁶
- Interview each:
 - Respondent
 - Complainant
 - 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)
- Record or transcribe each interview
- Provide the recording or transcript to the interviewee for correction
- Include the recording or transcript in the record of the investigation²⁷

²⁵ 42 CFR 93.310(e)

²⁶ 42 CFR 93.310(f)

²⁷ 42 CFR 93.310(q)

• 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 completion²⁸.

Time for Completion of Investigation

The investigation is to be completed within 120 calendar days of initiation²⁹ (initiation is considered the first investigation committee meeting³⁰), including:

- Conducting the investigation
- Preparing the report of findings
- Providing the draft report for comment
- · Sending the final report to ORI/OIG

However, if the RIO determines that the investigation will not be completed within the required period, he/she will:

PHS³¹:

• Submit to ORI 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.

NSF³²:

• If the institution wishes NSF deferral of independent investigation to continue, OIG will be notified, and may require submission of periodic status reports.

Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that³³:

- Describes:
 - $\circ\hspace{0.4cm}$ The nature of the allegation of research misconduct, including identification of the respondent
 - And documents the PHS or other funding agency support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support
 - o The specific allegations of research misconduct considered in the investigation

^{28 42} CFR 93.310(h)

²⁹ 180 days for NSF research; 45 CFR 689.4(b)(4)

³⁰ The first investigation committee meeting must take place no more than 30 days following the decision by the inquiry committee that an investigation is warranted.

^{31 42} CFR 93.311

^{32 45} CFR 689.4 (4)

³³ 42 CFR 93.313.

- 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
- Includes a statement of findings for each allegation of research misconduct identified during the investigation.
- Each statement of findings must:
 - o Identify whether
 - the research misconduct was falsification, fabrication, or plagiarism, and
 - it was committed intentionally, knowingly, or recklessly
 - o Summarize the facts and the analysis that supports the conclusion
 - 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)
 - o Identify:
 - specific PHS support
 - whether any publications need correction or retraction
 - The person(s) responsible for the misconduct
 - List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies³⁴

Comments on the Draft Report and Access to Evidence

Respondent:

The RIO/designee 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 calendar days from the date he/she received the draft report to submit comments to the RIO/designee. The respondent's comments must be included and considered in the final report³⁵.

Complainant:

Investigation reports are not routinely provided to the complainant. On a case-by-case basis as determined by the RIO, the institution may provide relevant portions of the draft investigation report to the complainant for comment. If the complainant is asked to comment, responses must be received within 30 days and must be included and considered in the final report.

Confidentiality:

In distributing the draft report, or portions thereof, the RIO/designee will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable

_

^{35 42} CFR 93.312(a) and 93.313(g)

conditions to ensure such confidentiality. For example, the RIO/designee may require that the recipient sign a confidentiality agreement.

Decision by Deciding Official

The RIO will:

- Assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered
- Transmit the final investigation report to the DO/DO's designee, with a copy to the Provost

The DO will determine in writing:

- Whether the institution accepts the investigation report and its findings
- The appropriate administrative actions³⁶ in response to the accepted findings of research misconduct.

If the DO's determination varies from the findings of the investigation committee, the DO 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 may return the report to the investigation committee with a request for further fact-finding or analysis. The final determination might slightly alter the investigation report provided by the investigation committee.

When a final decision on the case has been reached:

- The RIO will normally notify both the respondent and the complainant in writing that the proceeding has been closed.
- The respondent will be provided with the institutional findings, as well as associated institutional administrative actions, if any.
- After informing ORI or NSF OIG or DOD as applicable, the DO/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,

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found
- For the person responsible for the misconduct:
 - o Removal of the responsible person from the particular project
 - Letter of reprimand
 - Special monitoring of future work
 - Probation
 - Suspension
 - Salary reduction
 - o Initiation of steps leading to possible rank reduction or termination of employment
- Restitution of funds to the grantor agency as appropriate
- Other actions appropriate to the research misconduct

³⁶ Examples of such actions may include, but are not limited to:

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

Appeals

Within 15 calendar days of receipt of the findings, the respondent may appeal the decision in writing to the Deciding Official. The Deciding Official may request that the RIO reconvene the investigation committee to review the appeal or may require that a separate committee be convened to reopen the matter. Appeals related to PHS-funded research activities must be addressed within 120 calendar days.

Notice to ORI/OIG/DOD of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the allowed period for completing the investigation, submit to ORI or NSF OIG or DOD as applicable³⁷:

- A copy of the final investigation report with all attachments
- A statement of whether the institution:
 - Accepts the findings of the investigation report
 - o Found misconduct and, if so, who committed the misconduct
- A description of any pending or completed administrative actions against the respondent
- Investigation reports are provided to funding agencies based on agency requirements. Substantiated research misconduct in unfunded research is not federally reported, but might be reported externally based on the final administrative sanctions determined by the DO/designee (for example, journal retractions, collaborators, professional societies). In most of these cases, the full investigation report is not released.

Reporting Premature Closures

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:

- The respondent has admitted guilt, see **Admission of Misconduct**, above.
- A settlement with the respondent has been reached

Or for any other reason except:

 Closing of a case at the inquiry stage on the basis that an investigation is not warranted, or

^{37 42} CFR 93.315

 A finding of no misconduct at the investigation stage, which must be reported to ORI or to NSF OIG as applicable, as prescribed in this policy and 42 CFR 93.315 and 42 CFR 93.316(a)

Record Retention

Retention of the Research Misconduct Records

The RIO will maintain records of research misconduct proceedings as defined by 42 CFR 93.317³⁸. Unless custody has been transferred to HHS or NSF, or ORI or OIG has advised in writing that the records no longer need to be retained, records of research misconduct proceedings will be maintained in a secure manner for 7 years after completion of:

- The proceeding
- Any PHS³⁹ or OIG proceeding involving the research misconduct allegation.

ORI or OIG may request records to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation⁴⁰. If requested, the RIO is responsible for providing applicable information, documentation, research records, evidence, or clarification.

Proceedings under DoD oversight will follow DoDI 3210.7, E4.1.8.41

⁻

³⁸Definition of research misconduct proceedings: **(1)** The records that the institution secures for the proceeding, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained; **(2)** The documentation of the determination of irrelevant or duplicate records; **(3)** The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; **(4)** The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted; and **(5)** The complete record of any institutional appeal.

³⁹ 42 CFR 93.317(b)

⁴⁰ 42 CFR 93.300(g), 42 CFR 93.403(b) and (d), 45 CFR 689.9(a)

⁴¹ DoDI 3210.7, E4.1.8: The institution must maintain the following documents related to an allegation of research misconduct: Written statement of the original allegation; Formal notification to the subject of the allegation; Written outcome of the inquiry phase and supporting documentation; Written report of the investigation, including the evidentiary record and supporting documentation; and if applicable, statement of recommended corrective actions and any response thereto, including any corrective action plan. The documents specified in above are considered project-related records that must be retained for 3 years after the final decision.