

A-02 Operations

A-02-32 Scientific Misconduct Policy

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OMRF Policy for Responding to Allegations of Scientific Misconduct

A. Introduction*

1. General Policy

All faculty, staff, trainees and students involved in research at OMRF are required to maintain the highest standards of ethical conduct in research and to adhere to the rules and regulations of federal agencies governing biomedical research. This commitment to integrity requires intellectual honesty in conducting and reporting research.

2. Scope

- a. This policy and the associated procedures apply to all individuals at OMRF engaged in research including that supported by or for which support is requested from PHS and all other public and/or private agencies that support research at OMRF. The PHS regulation at 42 C.F.R. Part 93 applies to any research, research-training or research-related grant or cooperative agreement or any applications or proposals for such support with PHS. It applies to activities related to that research and research training such as the operation of tissue and data banks and the dissemination of research information. (93.102)
- b. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, affiliates, guest researchers, or collaborators at OMRF. This may include support staff, volunteers, and contractors, subcontractors, and sub-awardees and their employees. (93.214)
- c. This policy and associated procedures will apply to plagiarism of research records produced in the course of the US Public Health Service (PHS) supported research, research training or activities related to that research or training. (93.102)

- d. The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of OMRF and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the president of OMRF.

* Sections that are based on requirements of the PHS regulations codified at 42 C.F.R. Part 93 with subsection references as indicated.

- e. This policy and associated procedures do not apply to authorship or collaboration disputes.

B. Requirements for Findings of Research Misconduct

A finding of research misconduct requires that:

1. There must be a significant departure from accepted practices of the relevant research community; and
2. The misconduct must be committed intentionally, knowingly, or recklessly; and
3. The allegation must be proven by a preponderance of the evidence. (93.104)
4. Research misconduct must have occurred within six years of the date that the allegation is received by the institution with the following exceptions:
 - a. The respondent continues, renews or benefits from the research record that is alleged to have been falsified, fabricated or plagiarized.
 - b. If it is determined by the Office of Research Integrity, PHS (“ORI”) or the institution in consultation with ORI that the alleged misconduct would possibly have an adverse effect on the health or safety of the public. (93.105)

C. Definitions

1. **Allegation** means any written or oral statement or other indication of possible research misconduct made to an institutional or US Department of Health and Human Services (DHHS) official.
2. **Complainant** means a person who in good faith makes an allegation of research misconduct.
3. **Conflict of interest** means the real or apparent interference of one person’s interests with the interests of another person, where potential bias

may occur due to prior or existing personal, professional or financial relationships.

4. **Deciding Official (DO)** means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The DO will not be the same individual as the RIO and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. The DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.
5. **Fabrication** means making up data or results and recording or reporting them. (93.103)
6. **Falsification** means 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. (93.103)
7. **Good faith allegation** means 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. (93.210)
8. **Inquiry** means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation. (93.212)
9. **Investigation** means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct. It may include an administrative action recommendation. (93.215)
10. **ORI** means the Office of Research Integrity, the office within the DHHS that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service. (93.217)
11. **PHS** means the U.S. Public Health Service, an operating unit within the Department of Health and Human Services including the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration and the offices of the Regional Health Administrators. (93.220)

12. **PHS regulation** means 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 93.
13. **PHS support** means PHS funding, or applications or proposals therefore for biomedical research including salaries and other payments for grants, contracts, training, or cooperative agreements or applications. (93.221)
14. **Plagiarism** is the appropriation of another person's ideas, processes, results or words without giving appropriate credit. (93.103)
15. **Preliminary Assessment** is the initial assessment of the Research Integrity Officer of whether there is sufficient evidence to warrant an inquiry.
16. **Preponderance of the Evidence** means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. (93.219)
17. **Research Integrity Officer ("RIO")** means the institutional official with primary responsibility for assessing allegations of research misconduct covered under 42 CFR Part 93 and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
18. **Research record** means any data or results; including 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 also 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. (93.224)
19. **Respondent** means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation. (93.225)
20. **Retaliation** means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding. (93.226)

21. **Research misconduct or misconduct in science** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data, nor does it include disputes over authorship. (93.103)

D. Rights and Responsibilities

1. Research Integrity Officer

The Director of Research Administration/Compliance Officer at OMRF will serve as the RIO and will have primary responsibility for implementation of the procedures set forth in this document. The RIO will:

- a. consult confidentially with persons uncertain about whether to submit an allegation of research misconduct,
- b. receive allegations of research misconduct and immediately make a Preliminary Assessment of the allegation to determine if it is in accordance with the definition of research misconduct, whether there is sufficient evidence to warrant an inquiry, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether PHS support or PHS applications for funding are involved,
- c. notify the respondent and provide opportunities for him/her to review/ comment/ respond to allegations, evidence, and committee reports,
- d. appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation,
- e. 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,
- f. provide confidentiality to those involved in the proceedings; monitor treatment of individuals who are cooperating in inquiries or investigations; and review instances of alleged retaliation for appropriate action, (93.108)
- g. assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources,

- h. keep the DO and others who need to know apprised of the progress of the review of the allegation of research misconduct,
- i. sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Sections F(2) and I(3) of this policy and maintain it securely in accordance with this policy and applicable law and regulation,
- j. report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public health or interest, (93.304(h)-(i)),
- k. notify ORI at any stage of the inquiry or investigation if:
 - (1) there is an immediate public health or safety hazard including a risk to human or animal subjects involved; (93.318(a))
 - (2) there are relevant facts needed to protect public health, Federal funds or equipment, and the integrity of the PHS supported research process; (93.304(i))
 - (3) PHS resources or interests are threatened; (93.318(b))
 - (4) research activities should be suspended (93.318(c))
 - (5) there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any; (93.318(e))
 - (6) it is probable that the alleged incident is going to be reported publicly; or
 - (7) there is a reasonable indication of possible civil or criminal violation. In the case of civil or criminal implications, the institution must inform ORI within 24 hours of obtaining that information. (93.318(d))
- l. assure compliance with written policies in accordance with CFR 42 §93 on behalf of the institution, (93.301)
- m. Inform and educate all research investigators involved with PHS supported biomedical research or training about these policies, (93.302(2)(i))

- n. submit an annual report with ORI and any other information requested by ORI on misconduct proceedings and the institution's compliance, (93.302(b)-(c)) and
- o. assist in administering and enforcing any HHS administrative actions imposed on its institutional members. (93.300(h))

2. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. Specifically, the complainant:

- a. will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation in the terms and conditions of their employment or other status at the institution.
- b. may be given the opportunity to comment on any portions of the draft report if the RIO has determined that the complainant may be able to provide pertinent information.
- c. must be interviewed during an investigation and given the transcript or recording of the interview for correction. (93.310(g))
- d. should immediately report any alleged or apparent retaliation to the RIO.
- e. will have privacy protected by the institution to the maximum extent possible when misconduct is reported in good faith. For example, if the complainant requests anonymity, the institution will make every effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.

3. Respondent

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

- a. will be informed in writing of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be

interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to provide comments for attachment to the reports. (93.307(b))

- b. will be given copies of, or reasonable supervised access to research records where appropriate. (93.305(b))
- c. Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or the thorough carrying out of the inquiry or investigation. (93.108)
- d. If the respondent is not found guilty of research misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation. (93.304(k))

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 institutional officers, the DO may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.

4. Deciding Official

- a. The President of OMRF will serve as the DO and will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report.
- b. The DO will consult with the RIO or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

E. General Policies and Principles

1. Responsibility to Report Misconduct

All employees or individuals associated with OMRF should report observed, suspected, or apparent misconduct in science to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the RIO at 271-7858 to discuss the suspected misconduct informally. 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 problem. At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with

the RIO and will be counseled about appropriate procedures for reporting allegations.

2. Cooperation with Inquiries and Investigations

OMRF employees will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO or other institutional officials on misconduct allegations. (93.300)

F. Conducting the Inquiry

1. Initiation and Purpose of the Inquiry (93.307)

- a. Upon a Preliminary Assessment finding that the allegation provides information to allow specific follow-up, involves PHS support, is credible and specific so that potential evidence of research misconduct may be identified, and falls under the PHS definition of research misconduct, the RIO will immediately initiate the inquiry process.
- b. In initiating the inquiry, the RIO should clearly identify the original allegation and any related issues that should be evaluated.
- c. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.
- d. At the time of or before beginning the inquiry, the RIO must notify the presumed respondent in writing.

2. Sequestration of the Research Records

- a. Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, the RIO must take all reasonable and practical steps to obtain all original research records and materials relevant to the allegation, and immediately inventory and secure such materials. The RIO may consult with ORI for advice and assistance in this regard. (93.305)
- b. As additional research records or evidence is discovered during the course of the research conduct proceeding, these materials will also be taken in custody. Custody may be limited to copies where research records or equipment is shared by a number of users so long as those

copies are substantially equivalent to the evidentiary value of the instruments.

3. Appointment of the Inquiry Committee

- a. The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within ten (10) days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have unresolved personal, professional or financial conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.
- b. The RIO will notify the respondent of the proposed committee membership in ten (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 five (5) days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

4. Charge to the Committee and the First Meeting

- a. The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the Preliminary Assessment and states that the purpose of the inquiry is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS regulation. The purpose is to determine whether an allegation has enough substance to warrant an investigation and doesn't require a full review of all related evidence. An inquiry is not to discover whether research misconduct definitely occurred or who was responsible. (93.307(c)-(d))
- b. 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 and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.
- c. The RIO will set a deadline for the completion of the inquiry and inform the committee that they are responsible for preparing a

written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309.

- d. The full inquiry process including 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 inquiry unless the RIO approves an extension. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period. The respondent will be notified of any extension.
- e. The RIO will be present or available throughout the inquiry to advise the committee as needed.

5. Inquiry Process

- a. The inquiry committee will normally interview the complainant, the respondent and key witnesses as well as examine relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry.
- b. After consultation with the RIO and, if necessary, institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation.
- c. The scope of the inquiry does not include deciding whether misconduct occurred or 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. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. (93.316)

G. The Inquiry Report

1. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and position of the respondent, the allegations; the PHS support including grant numbers, grant applications, contracts and publications listing PHS support; the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency. (93.307(e) & 93.309(a))

2. **Comments on the Draft Report by the Respondent and the Complainant**

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

- a. **Confidentiality:** The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report.
- b. **Receipt of Comments:** Within ten (10) calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

3. **Inquiry Decision by DO**

- a. The RIO will transmit the final inquiry report and any comments to the DO, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation.
- b. The inquiry is completed when the DO makes this determination, which must be made within sixty (60) days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.
- c. If the DO decides an investigation is not warranted, the RIO shall secure sufficiently detailed documentation of inquiries to permit a later assessment by ORI of reasons for this decision. These records must be kept in a secure manner for at least 7 years after the termination of the inquiry. These documents must be provided to ORI or other authorized HHS personnel upon request. (93.309(c))

H. **Notification of Decision for Investigation**

1. The RIO will notify respondent in writing of the allegations within a reasonable amount of time before the investigation begins. Respondent will also be given written notice of any new allegations identified during the inquiry. (93.310(c))
2. The RIO will notify ORI of any decision to open an investigation on or before the date on which the investigation begins and within 30 days of finding that an investigation is warranted. ORI will be notified of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process.

3. The RIO will also notify all appropriate institutional officials of the DO's decision.

I. Conducting the Investigation (93.310)

1. Criteria Warranting Investigation

- a. There is reasonable basis for concluding the allegation is within the definition of research misconduct and involves PHS supported biomedical research, training or activities.
- b. The fact finding and information gathering during the inquiry indicate that the allegation may have substance.

2. Purpose of the Investigation

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

3. Sequestration of the Research Records

- a. 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.
- b. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured.
- c. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

4. Appointment of the Investigation Committee

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

5. Charge to the Committee and the First Meeting

- a. Charge to the Committee
 - (1) The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and any related issues identified during the inquiry, defines research misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.
 - (2) During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the RIO, who will notify the respondent in writing of the new subject matter. The RIO will provide notice to additional respondents if necessary.
 - (3) 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:

- (a) Research misconduct occurred and that respondent has not proven any affirmative defenses, including honest error or difference of opinion, by a preponderance of the evidence,
- (b) The research misconduct is a significant departure from accepted practices of the relevant research community,
- (c) The respondent committed the research misconduct intentionally, knowingly, or recklessly.

b. The First Meeting

- (1) 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 developing a specific investigation plan.
- (2) The RIO will emphasize the need for protection of the confidentiality of respondents, complainants and research subjects.
- (3) The investigation committee will be provided with a copy of this policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

6. Investigation Process

- a. The investigation committee will be appointed and the process initiated within thirty (30) days of the completion of the inquiry.
- b. The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.
- c. The investigation will pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct.
- d. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other

interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

J. The Investigation Report

1. Elements of the Investigation Report (93.313 & 93.315)
 - a. The final report submitted by the RIO to ORI must describe the nature of the allegations, document PHS support (current or proposed), the policies and procedures under which the investigation was conducted, specific allegations of research misconduct, and how and from whom information relevant to the investigation was obtained.
 - b. It must identify and summarize research records and evidence taken into custody and also identify any evidence taken but not reviewed.
 - c. It must state the findings for each separate allegation of research misconduct while identifying the type of misconduct (falsification, fabrication or plagiarism) and whether it was committed intentionally, knowingly or recklessly; and explain the basis for the findings by summarizing the facts and analysis supporting the conclusion.
 - d. It must 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.
 - e. It must identify any publications that need correction or retraction.
 - f. It must identify the person(s) responsible for the misconduct.
 - g. It must list any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.
 - h. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.

2. Comments on the Draft Report

a. Respondent

The RIO will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed thirty (30) days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence. The respondent will be advised of the confidentiality of the report and may be required to sign a confidentiality agreement.

b. Complainant

The RIO may provide the complainant, if he or she is identifiable, with those relevant portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments. The complainant must submit any comments within thirty (30) days of the date on which the draft was received. The complainant will be advised of the confidentiality of the report and may be required to sign a confidentiality agreement.

c. Institutional Counsel

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

3. Institutional Review and Decision

- a. The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's, and complainant's if applicable, comments are included and considered, and transmit the final investigation report to the DO, 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 will, as part of his/her written determination, explain in detail the basis for rendering a different opinion from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further facing-finding or analysis. The DO's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

- b. When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. In addition, the DO 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.
- c. All practical and reasonable efforts as appropriate will be made to protect or restore the reputation of persons alleged to have engaged in research misconduct who are found innocent.
- d. All reasonable and practical efforts will be made to protect or restore the position and reputation of any complainant, witness or committee member and to counter potential or actual retaliation.

4. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the DO for approval, and submitting the report to the ORI. (93.311(a))

K. Completion of Cases; Requirements for Reporting to ORI

1. The RIO must give ORI the investigation report with all attachments and appeals, a statement of whether the institution found research misconduct and who committed it, a statement whether the institution accepts the investigation's findings and a statement describing any pending or completed administrative actions against the respondent. (93.315)
2. The institution will provide full and continuing cooperation with ORI during its oversight review or any subsequent administrative hearings or appeals. This includes providing research records and evidence under the institution's control, custody or possession and access to all persons within its authority necessary to develop a complete record of evidence.
3. The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined in 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, record of research misconduct proceedings must be maintained in secure manner for seven (7) years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. 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.

4. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. If an institution 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 in advance, including a description of the reasons for the proposed termination. (93.316(a))
5. If the institution 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. (93.311(b))
6. 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 funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

L. Institutional Administrative Actions

The Oklahoma Medical Research Foundation will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the DO determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The actions may include:

1. withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found,
2. 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,
3. restitution of funds as appropriate, or
4. other actions appropriate to the research misconduct.

M. Other Considerations

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

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

2. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the RIO will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the DO.

3. Protection of the Complainant and Others

Regardless of whether the institution or ORI determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the DO will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The RIO is responsible for implementing any steps the DO approves. The RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant. (93.300(d) & 93.304(l))

4. 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. If an allegation was not made

in good faith, the DO will determine whether any administrative action should be taken against the complainant.

5. **Interim Administrative Actions**

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out. (93.304(h))