OKLAHOMA STATE DEPARTMENT OF HEALTH
ADMINISTRATIVE PROCEDURES MANUAL

NUMBER: 1-40A
TITLE: Research Integrity
ADOPTED: October 2013
LAST REVIEWED: October 2013
RESPONSIBLE SERVICE: Prevention and Preparedness Services

APPROVED: _____
Terry Cline, Ph.D.
Commissioner
Signature on File

I. Purpose

The purpose of this administrative procedure is to describe the responsibilities of the Oklahoma State Department of Health (OSDH) under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This procedure is to inform OSDH employees and associated researchers of the agency's dedication to research integrity and protection of PHS funding. The OSDH values responsible conduct of research and maintains a position of preventing misconduct in research while protecting the positions and reputations of good faith complainants, witnesses, and committee members.

A. Allegations of Research Misconduct

This procedure applies to the allegations of research misconduct involving:

1. 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 OSDH and

    a. PHS supported biomedical or behavioral research, research training, or activities related to that research or research training, such as the operation of tissue or data banks and the dissemination of research information;

    b. Applications or proposals for PHS support were produced for biomedical or behavioral research, research training, or activities related to that research or research training; or

    c. Plagiarism of research records produced in the course of PHS supported research, research training, or activities occurred 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.

This administrative procedure aligns with the procedure established by the Oklahoma State Administrative Rules, Title 310, Chapter 10, Subchapter 7, Research Integrity, and will be followed when an allegation of possible misconduct in science is received by the Research Integrity Officer or by an OSDH official. Particular circumstances in an individual case may dictate variation from this procedure deemed in the best interests of the OSDH and PHS. Any change from this procedure also must ensure fair treatment to the subject of the inquiry or investigation. The Commissioner of Health shall approve any significant variation, as appropriate, in advance.

II. Research Misconduct

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

A. Research Misconduct Definitions

1. Fabrication - making up data or results and recording or reporting them;

2. 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; and or

3. Plagiarism - appropriating another person's ideas, processes, results, words without giving appropriate credit.

III. Research Integrity Officer (RIO)

A. General Responsibilities

The RIO is the OSDH official responsible for:

1. Assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of misconduct may be identified;

2. Overseeing inquiries and investigations;

3. Annually maintaining an active assurance, which ensures the U.S. Department of Health and Human Services Office of Research Integrity (ORI) that the OSDH will follow the written procedures for handling research misconduct and report accordingly to ORI;

4. Filing an annual report with ORI;

5. Informing OSDH employees, agents, and affiliates about the research integrity procedure for responding to allegation of research misconduct by providing the procedure to all researchers approved by the OSDH Institutional Review Board for research and to all OSDH personnel seeking to publish or present study results; and by posting the procedure on the OSDH website and intranet site; and

6. Performing all other RIO responsibilities described in this administrative procedure.

B. Qualifications

The RIO will be an employee of OSDH who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith. The Commissioner of Health shall appoint the RIO. Pam Archer has been appointed and has primary responsibility for implementation of this procedure. Ms. Archer may be contacted by phone at (405) 271-9444 x30594 or by email at pama@health.ok.gov.

C. Appointment of the Inquiry and Investigation Committees

The RIO will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will do everything possible to ensure that confidentiality is maintained.

D. Assistance to the Inquiry and Investigation Committees and Employees

The RIO will assist inquiry and investigation committees and all employees in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO shall maintain files of all documents and evidence and shall maintain the confidentiality and the security of the files.

E. Response to Allegations of Research Misconduct

The RIO will ensure that the response to each allegation of research misconduct is conducted in a thorough, competent, objective, and fair manner.

F. Report to ORI

The RIO will report to ORI and shall keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential PHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

IV. Complainant

The complainant is the person who makes an allegation of research misconduct.

A. Complainant Opportunities

The complainant will have the opportunity to:

1. Testify before the inquiry and investigation committees;
2. Review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony;
3. Be informed of the results of the inquiry and investigation; and
4. Be protected from retaliation.

B. Complainant Review

If the RIO has determined that the complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the complainant for comment.

C. Complainant Responsibilities

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

V. Respondent

The respondent is the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

A. Respondent Rights

The respondent will:

1. Be informed in writing of the allegations when an inquiry or investigation is opened;

2. Be interviewed by and present evidence to the inquiry and investigation committees, as applicable;

3. Review and comment on the draft inquiry and investigation reports;

4. Have the right to advice of counsel; and

5. Be notified in writing of the final determinations and resulting actions.

B. Respondent Responsibilities

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. If the respondent is not found guilty of research misconduct, he/she has the right to receive assistance from OSDH in restoring his/her reputation.

VI. Deciding Official

A. Deciding Official Responsibilities

The deciding official (DO) is the OSDH official who makes final determinations on allegations of research misconduct and any administrative actions. The DO will not be the same individual as the RIO and should have no direct prior involvement in the OSDH's inquiry, investigation, or allegation assessment. A 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. The DO for the OSDH is the Commissioner of Health.

B. Deciding Official Determinations

The DO will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. 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, and whether to take other appropriate administrative actions.

VII. Responsibility to Report Misconduct

All employees or individuals associated with OSDH 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 contact the RIO 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 be counseled about appropriate procedures for reporting allegations.

VIII. Confidentiality

The RIO shall 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. The RIO shall, 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 no further disclosure of identifying information.

IX. Protecting the Complainant and Others

A. Monitor Treatment

The RIO will monitor the treatment of individuals who bring allegations of misconduct or of inadequate OSDH response, and the treatment of those who cooperate in inquiries or investigations.

B. Retaliation Prohibited

The RIO will ensure that complainants, witnesses, and committee members will not be retaliated against in the terms and conditions of their employment or other status at the OSDH and will review instances of alleged retaliation for appropriate action. A grievance may be filed by the complainant, witnesses or committee members or the RIO may file the grievance for them.

C. Reports of Alleged or Apparent Retaliation

Employees should immediately report any alleged or apparent retaliation to the RIO.

D. Protect Privacy

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

X. Protecting the Respondent

A. Inquiries and Investigations

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

B. OSDH Employees Accused of Research Misconduct

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

XI. Cooperation with Inquiries and Investigations

OSDH employees will cooperate with the RIO and other OSDH officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO and other OSDH officials on misconduct allegations.

XII. Conducting the Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether there is sufficient evidence to allow specific follow-up and warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of research misconduct. If the RIO determines that the allegation provides sufficient information to allow specific follow-up, involves

PHS support, and is within the PHS definition of research misconduct, he/she will immediately initiate the inquiry process. On or before the date the respondent is notified of the allegation, the RIO shall obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceedings according to section XIII part B.

XIII. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

In initiating the inquiry, the RIO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible 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. An inquiry does not require full review of all evidence related to the allegation.

B. Notice to Respondent and Sequestration of the Research Records

After determining that an allegation falls within the definition of research misconduct and involves PHS funding, the RIO must make a good faith effort to notify the respondent in writing. The RIO must also take all reasonable and practical steps to obtain and secure all research records and materials relevant to the allegation. The RIO may consult with OSDH counsel and/or ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

1. The RIO, in consultation with other OSDH officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee shall consist of individuals who:

    a. Do not have real or apparent conflicts of interest in the case;

    b. Are unbiased; and

    c. Have the necessary expertise to evaluate the evidence and issues related to the allegation. These may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the OSDH.

2. The RIO shall notify the respondent of the proposed committee membership within 10 days of appointment of all members.

3. If the respondent submits a written objection to any appointed member of the inquiry committee based on bias or conflict of interest within 5 days of notification of the committee membership, the RIO shall determine whether to replace the challenged member with a qualified substitute.

D. Informing the Committee at the First Meeting

At the first meeting the RIO will:

1. Set forth the time for completion of the inquiry

2. Describe the allegations and any related issues identified during the allegation assessment;

3. State the purpose of the inquiry;

4. State 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; and

5. Inform the committee that they are responsible for preparing or directing the preparation of a written report of the inquiry.

The RIO will assist the committee with organizing plans for the inquiry and answer any questions raised by the committee. The RIO and OSDH counsel will be present or available throughout the inquiry to advise the committee, as needed.

E. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses and examine relevant research records and materials. Interviews will be recorded and transcribed. The transcript will be provided to each interviewed person for any corrections. The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and OSDH counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation.

XIV. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared by the inquiry committee and RIO that includes:

1. The name and title of the respondent;

2. The name and title of the committee members;

3. A description of the allegations;

4. The PHS support;

5. A summary of the inquiry process;

6. A list of the research records reviewed;

7. Summaries of any interviews;

8. A description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and

9. Any comments from the complainant or respondent.

OSDH counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Complainant

After redacting the identity of the complainant, the RIO will provide the respondent with a copy of the redacted draft inquiry report for comment and rebuttal. The RIO will also provide the complainant with portions of the draft inquiry report that address the complainant's role and opinions in the investigation.

C. Confidentiality

The RIO shall establish reasonable conditions for review to protect the confidentiality of the draft report.

D. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee will revise the report as appropriate.

XV. Inquiry Decision and Notification

A. Decision by Deciding Official

The RIO will provide 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. Any finding that an investigation is warranted must be made in writing by the DO.

B. Notification

The RIO will notify both the respondent and the complainant in writing of the DO's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The respondent will be notified in writing of allegations to be investigated, including any new allegations of research misconduct. If the inquiry identifies additional respondents, they must also be notified in writing. Additional records will be sequestered, if needed, according to section XVII part B below. The RIO will also notify all appropriate OSDH officials of the DO's decision. If an investigation is to be conducted, the RIO will notify ORI within 30 days (on or before the investigation begins) of the decision and provide ORI a copy of the inquiry report.

C. Confidentiality

A decision recommending further investigation pursuant to section A above shall be deemed to be confidential pursuant to Title 51 O.S., § 24A.12 and shall not be publically disseminated beyond the persons identified in section B above.

XVI. Time Limit for Completing the Inquiry Report

The inquiry process, including preparation of the final inquiry report and the decision of the DO, must be completed within 60 calendar days of its initiation, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent and complainant will be notified of the extension.

XVII. Conducting the Investigation

A. Initiation and Purpose of the Investigation

The investigation must begin within 30 calendar days after the determination by the DO that the investigation is warranted. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in-depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important when the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or

if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The RIO will take all reasonable and practical steps to 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 will be conducted. The need for additional sequestration of records may occur for any number of reasons, including the decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

1. The RIO, in consultation with other OSDH officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who:

    a. Do not have real or apparent conflicts of interest in the case;

    b. Are unbiased; and

    c. Have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the complainant, respondent, 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 OSDH.

2. Individuals appointed to the investigation committee may also have served on the inquiry committee. The RIO will notify the respondent of the proposed committee membership within 5 days of appointment of all members.

3. If the respondent submits a written objection to any appointed member of the investigation committee based on bias or conflict of interest within 5 days of notification of the committee membership, the RIO shall determine whether to replace the challenged member with a qualified substitute.

D. Informing the Committee and the First Meeting

1. Informing the Committee

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

a. Describes the allegations and related issues identified during the inquiry;

b. Identifies the name and position of the respondent;

c. Defines research misconduct;

d. Informs the committee that it 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.

e. Informs the committee that in order to determine that the respondent committed research misconduct it must find a preponderance of evidence that establishes: 1) research misconduct occurred; 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; and

f. Informs the committee that it must prepare or direct preparation of a written investigation report.

g. Inform the committee that 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 determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The RIO, with the assistance of OSDH counsel, will convene the first meeting of the investigation committee to review the information provided to the committee, 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 procedure and the PHS regulation. The

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

E. Investigation Process

The investigation committee and RIO must:

1. 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;

2. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

3. 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

4. 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.

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. 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 should be recorded and transcribed. Transcripts of the interviews will be prepared and provided to the interviewed persons for correction, and included as part of the investigatory file.

XVIII. The Investigation Report

A. Elements of the Investigation Report

A written draft investigation report must be prepared by the investigation committee and the RIO that includes:

1. The name and title of the respondent;

2. The name and title of committee members;

3. A description of the nature of the allegation of research misconduct;

4. A description and documentation of PHS support (grant numbers, applications, contracts, and publications);

5. The specific allegations of research misconduct considered in the investigation;

6. How and from whom information relevant to the investigation was obtained;

7. The policies and procedures used to conduct the investigation;

8. A summary of the research records and evidence reviewed and any evidence taken into custody that was not reviewed;

9. A statement of findings for each separate allegation of research misconduct identified during the investigation on whether research misconduct did or did not occur. Each statement of findings must:

    a. Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;

    b. 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 the respondent to establish by a preponderance of evidence that he/she did not engage in research misconduct because of honest error or a difference of opinion;

    c. Identify the specific PHS support;

    d. Identify whether any publications need correction or retraction;

    e. Identify the person(s) responsible for the misconduct; and

    f. List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

10. Comments from the complainant and respondent; and

11. A description of any sanctions imposed and administrative actions taken by OSDH.

B. Review by OSDH Counsel

The RIO will provide the draft investigation report to OSDH counsel for a review of its legal sufficiency. Comments will be incorporated into the report as appropriate.

C. Comments on the Draft Report

1. Respondent

   After redacting the identity of the complainant, the RIO will provide the respondent with a redacted 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 up to 30 days to review and submit comments on the draft report to the RIO. The respondent's comments must be attached and considered in the final report.

2. Complainant

   The RIO will provide the complainant with the portions of the draft investigation report that are pertinent to the complainant for comment. The complainant will be allowed up to 30 days to review and submit comments on the draft report to the RIO. The complainant's comments must be attached and considered in the final report.

3. Confidentiality

   In distributing the draft report, or portions thereof, to the respondent and complainant, the RIO will inform them 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 request the recipient and complainant to sign a confidentiality statement or come to his/her office to review the report. The identity of the complainant will be subject to public disclosure only as the RIO may determine is reasonable and appropriate by balancing the needs of the complainant to remain confidential with the need to comply with federal regulations.

D. Review and Decision

The final investigation report, including the respondent and complainant's comments, will be provided to the DO. Based on a preponderance of the evidence, the DO will make the final determination whether to accept the investigation report, its findings, and the recommended actions. The DO will document this determination in writing as well as the appropriate

actions in response to the accepted findings of research misconduct. If the DO's determination varies from that of the investigation committee, the DO will explain in detail the basis for rendering a decision different from that of the investigation committee. The DO's explanation should be consistent with the PHS definition of research misconduct, the OSDH's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The DO may also return the report to the investigation committee with a request for further fact-finding or analysis. The DO's written determination, together with the investigation committee's report, constitutes the final investigation report.

E. Notification

When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. After the RIO notifies ORI of the decision, 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. The respondent shall be notified of any actions.

F. Transmittal of the Final Investigation Report to ORI

The RIO shall transmit to ORI:

1. A copy of the final investigation report with all attachments;

2. An explanation of significant variations from the OSDH procedure, if any;

3. A statement of whether OSDH accepts the findings of the investigation report;

4. A statement of whether OSDH found misconduct and, if so, who committed the misconduct; and

5. A description of any pending or completed administrative actions against the respondent.

G. Time Limit for Completing the Investigation Report

An investigation should normally 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

respondent and complainant for comment, submitting the report to the DO for approval, and submitting the report to ORI. If the investigation cannot be completed within 120 days, an extension must be requested in writing from ORI. The request will explain the delay and provide a report on progress, estimate the date of completion of the report, and describe other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by ORI.

XIX. Additional Requirements for Consultation and Reporting to ORI

A. Written Request to ORI to Terminate the Inquiry or Investigation

If the inquiry or investigation is terminated for any reason without completing all relevant requirements, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

B. ORI Consultation

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, an admission of research misconduct cannot be accepted as a basis for closing the case or not undertaking an investigation without prior approval from ORI.

C. ORI Notification of Specified Circumstances

The RIO will notify ORI at any stage of the inquiry or investigation if:

1. There is an immediate health hazard involved;

2. There is an immediate need to protect Federal funds or equipment;

3. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

4. It is probable that the alleged incident is going to be reported publicly;

5. The allegation involves a public health sensitive issue, such as a clinical trial; or

6. There is a reasonable indication of possible criminal violation. The OSDH must inform ORI within 24 hours of obtaining criminal violation information.

XX. OSDH Administrative Actions

A. Administrative Action

OSDH 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/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 resulting 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; and

3. Restitution of funds as appropriate.

B. Termination of OSDH Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's OSDH 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. 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.

C. Restoration of the Respondent's Reputation

If the OSDH 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 OSDH actions to restore the respondent's reputation must first be approved by the DO.

D. Protection of the Complainant and Others

Regardless of whether the OSDH 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.

E. 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.

F. Interim Administrative Actions

OSDH 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.

XXI. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the reports and records of the inquiry and investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will maintain and dispose of the records of any inquiry or investigation in compliance with the approved OSDH records retention schedule for the Office of the Commissioner of Health; however, the records must be maintained for at least 7 years after completion of the proceeding or completion of any PHS proceeding involving the research misconduct allegation. ORI personnel will be provided access to the records upon request. These records are subject to public review or copying unless otherwise exempt from disclosure pursuant to the Oklahoma Open Records Act.

XXII. Additional Guidelines

Sample Policy and Procedures for Responding to Allegations of Research Misconduct, Office of Research Integrity, U.S. Department of Health and Human Services.

XXIII. References

Code of Federal Regulations, Title 42, Part 93

Oklahoma State Administrative Rules, Title 310, Chapter 10, Subchapter 7

Title 51 O. S., § 24A.12

XXIV. Action

The commissioner is responsible for ensuring the annual review of this administrative procedure.

The Office of Scientific and Research Integrity is responsible for the annual review and revision of this administrative procedure.

Any exceptions to this administrative procedure require prior written approval of the commissioner.

This procedure is effective immediately as indicated.

XXV. Attachments

None were identified.