Procedures for Responding
to Allegations of Research Misconduct
The University of Central Arkansas

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Appendices

I. Introduction

The purpose of these procedures is to provide advice to university officials on the methods and principles for assessing allegations and conducting inquiries and investigations related to possible research misconduct. These procedures also address requirements for reporting research misconduct investigations, adopting institutional actions in response to findings of research misconduct, and cooperating with the Federal Office of Research Integrity in its review of institutional actions and reports.

These procedures are intended to guide institutional officials responsible for assessing allegations, conducting inquiries and investigations, and reporting the results to appropriate agencies. The procedures do not create any right or benefit, substantive or procedural, enforceable at law by a party against the institution, its agencies, officers, or employees.

These procedures should be read and implemented in conjunction with the University of Central Arkansas Policy for Responding to Allegations of Research Misconduct.

II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible research misconduct made to an institutional official.

B. *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 or professional relationships.

C. *Deciding Official* means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Provost will serve as the Deciding Official.

D. *Employee* means, for the purpose of these instructions only, any person paid by, under the control of, or affiliated with the institution, including but not limited to faculty, scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

E. *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.

F. *Informant or whistleblower* means a person who makes an allegation of research misconduct.

G. *Inquiry* means information-gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

H. *Institutional counsel* means legal counsel who represents the institution during the research misconduct inquiry and investigation and who is responsible for advising the Research Integrity Officer, the inquiry and investigation committees, and the Deciding Official on relevant legal issues. The institutional counsel does not represent the respondent, the informant, or any other person participating during the inquiry, investigation, or any follow-up action, except the institutional officials responsible for

managing or conducting the institutional research misconduct process as part of their official duties.

I. *Investigation* means the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

J. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science" (Appendix E).

L. *Research*, as used herein, includes 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, social sciences, statistics, and research involving human subjects or animals.

M. *Research Integrity Officer (RIO)* means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing any inquiries and investigations. The Dean of the Graduate School will serve as the RIO.

N. *Research misconduct* is defined as 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.

O. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

P. *Respondent* means the person against whom an allegation of research misconduct is directed or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Q. *Retaliation* means any action that adversely affects the employment or other status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of research misconduct or of

inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

R. *Support or funding* means grants, contracts, or cooperative agreements, or application for funding.

III. General Procedures and Principles

A. Responsibility to Report Misconduct

All employees and individuals associated with the University who receive or learn of an allegation of research misconduct should immediately report the allegation to the Research Integrity Officer (RIO), the Research Compliance Coordinator, or the appropriate college dean, or department chairperson. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact any of the above individuals to discuss informally the suspected misconduct. Upon receiving a written allegation of misconduct, the RIO will promptly engage in an assessment of the allegation to determine whether it falls within the definition of research misconduct. If the circumstances described do not meet the definition of research misconduct, the RIO may refer the individual or allegation to other appropriate offices or officials with responsibility for resolving other types of misconduct.

B. Protecting the Informant

Institutional employees who receive or learn of an allegation of research misconduct will treat the informant with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the informant and other individuals who cooperate with the institution against retaliation. Employees will immediately report any alleged or apparent retaliation to the RIO. See *Responsible Whistleblowing: A Whistleblower's Bill of Rights* and *ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research*.

C. Protecting the Respondent

Institutional employees who receive or learn of an allegation of research misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 C.F.R. Part 50, Subpart A (Appendix E), and these procedures are followed. Employees will report significant deviations from these instructions to the RIO. The RIO will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Confidentiality

Institutional employees who make, receive, or learn of an allegation of research misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the informant, the respondent, and other affected individuals. The RIO may establish reasonable conditions to ensure the confidentiality of such information.

E. Responding to Allegations

In responding to allegations of research misconduct, the RIO and any other institutional official or employee with an assigned responsibility for handling such allegations will make diligent efforts to ensure that the following functions are performed.

1. Any allegation assessment, inquiry, or investigation is conducted in a timely, objective, thorough, and competent manner.

2. Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation.

3. Immediate notification is provided to appropriate officials if:

   a. there is an immediate health hazard involved;
   b. there is an immediate need to protect funds or equipment;
   c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
   d. it is probable that the alleged incident is going to be reported publicly;
   e. the allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
   f. there is a reasonable indication of a possible criminal violation. In this instance, the institution must inform ORI and/or the funding agency within 24 hours of obtaining that information.

4. Interim administrative actions are taken, as appropriate, to protect funds and the public health, and to ensure that the purposes of financial assistance are carried out.

F. Employee Cooperation

Institutional 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. Further, employees will cooperate with ORI and/or a funding agency in its conduct of inquiries and investigations, its oversight of institutional inquiries and investigations, and any follow up actions.

G. Evidentiary Standards

The following evidentiary standards apply to findings of research misconduct.

1. Burden of Proof

   The burden of proof for making a finding of research misconduct is on the institution.

2. Standard of Proof

Any institutional finding of research misconduct will be established by a preponderance of the evidence. This means that the evidence shows that it is more likely than not that the respondent committed research misconduct.

H. Completion of Process

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

I. Early Termination

If the institution plans to terminate an inquiry or investigation prior to completion of all the steps, and if funded, the RIO will notify ORI and/or the funding agency of the planned termination and the reasons therefore. ORI may review the information provided and advise the institution whether further investigation should be undertaken.

J. Referral of Non-Research Misconduct Issues

When the institution's review of the allegation identifies non-research misconduct issues, the RIO should refer these matters to the proper institutional, State, or Federal office for action. Issues requiring referral are described in Appendix A.

IV. Preliminary Assessment of Allegations

A. Allegation Assessment

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether the allegation falls under the institution's definition of research misconduct, whether there is sufficient evidence to warrant an inquiry, and whether support or applications for funding are involved. This should be completed within 14 days upon receiving an allegation of misconduct.

1. Definition

The allegation should be carefully reviewed to determine whether it potentially constitutes fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices for proposing, conducting or reporting research.

2. Sufficient evidence to proceed

There is not always sufficient evidence or information to permit further inquiry into the allegation. For example, an allegation that a scholar's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, an effort should be made to obtain more information before initiating an inquiry. This information may be sought from any reasonable source, including the informant, if known.

3. Supported or Funded Research

Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support. Additional requirements for PHS supported research are described in Appendices B, C, and D. For allegations involving funding from non-PHS agencies, the agency should be contacted for its specific requirements for dealing with allegations of research misconduct.

B. Referral of Other Issues

Regardless of whether it is determined that a research misconduct inquiry is warranted, if the allegation involves PHS support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation should be referred to the appropriate PHS or DHHS office. See Appendix A.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up, and falls under the institution's definition of research misconduct, he or she will immediately initiate the inquiry process. 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, informant, 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.

B. First Steps If an Inquiry Is Necessary

As soon as practicable after the RIO determines that an inquiry is required, he or she will:

1. secure the relevant research records;
2. notify the Deciding Official, institutional counsel, and the respondent;
3. appoint and charge the inquiry officer or committee; and
4. notify ORI if any of the conditions listed in section III.E.3 of these procedures are present.

The RIO or institutional counsel may consult with ORI or the non-PHS funding agency at any time regarding appropriate procedures to be followed.

C. Sequestration of the Research Records

1. Immediate Sequestration

If the relevant research records have not been obtained at the assessment stage, the RIO will immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of records.

2. Institutional Access

Research records produced under grants and cooperative agreements are the property of the institution, and employees cannot interfere with the institution's right of access to them. Under contracts, certain research records may belong to the funding agency, but the institution will be provided access to contract records in the custody of the institution for purposes of reviewing misconduct allegations.

3. Original Records

The documents and materials to be sequestered will include all the original items (or copies if originals cannot be located) that may be relevant to the allegations. These include, but are not limited to, research records as defined in section II.O of this document.

4. Sequestration of the Records from the Respondent

The RIO should notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with location and identification of the research records. The RIO should obtain the assistance of the respondent's supervisor and institutional counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification. In addition to securing records under the control of the respondent, the RIO may need to sequester records from other individuals, such as coauthors, collaborators, or informants. As soon as practicable, a copy of each sequestered record will be provided to the individual from whom the record is taken if requested.

5. Inventory of the Records

A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

6. Security and Chain of Custody

The RIO will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the institutional counsel.

D. Notification of the Respondent

1. Contents of Notification

The RIO will notify the respondent in writing of the opening of the inquiry. The notification should identify the research project in question and the specific allegations, define research misconduct, identify any funding involved, list the names of the members of the inquiry committee (if appointed) and experts (if any), explain the respondent's opportunity to challenge the appointment of a member of the committee or expert for bias or conflict of interest, to be assisted by their own counsel, to be interviewed, to present evidence to the committee, and to comment on the inquiry report; address the respondent's obligation as an employee of the institution to cooperate; describe the institution's policy on protecting the informant against retaliation and the need to maintain the informant's confidentiality during the inquiry and any subsequent proceedings.

2. Potential Respondents

If no specific respondent has been identified at this stage of the process, the RIO will notify each potential respondent that an inquiry will be undertaken, *e.g.*, each coauthor on a questioned article or each investigator on a questioned grant application. Alternatively, the RIO may consult with the institutional counsel on the proper notification under the circumstances.

E. Designation of an Official or a Committee to Conduct the Inquiry by the RIO

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

1. Use of an Inquiry Committee

In complex cases, the RIO will normally appoint a committee of three or more persons to conduct the inquiry, following the procedures set forth in section V.F.

2. Use of an Inquiry Official

In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the RIO may choose to conduct the inquiry personally, or designate another qualified individual to do so. In such cases, the inquiry official will nevertheless obtain the necessary expert and technical advice to consider properly all issues.

3. Inquiry Process

The inquiry, whether conducted by a committee or an individual, will follow each procedural step set forth below.

F. Appointment of the Inquiry Committee

If an inquiry committee is to be appointed, the RIO will use the following procedures:

1. Committee Membership

The RIO, in consultation with other institutional officials and personnel as appropriate, will appoint the committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of the institution.

2. Experts

The RIO, in consultation with the committee, will determine whether additional experts other than those appointed to the committee need to be consulted during the inquiry to provide special expertise to the committee regarding the analysis of specific evidence. In this case, the experts provide a strictly advisory function to the committee; they do not vote and generally do not interview witnesses. The experts chosen may be from inside or outside of the institution.

3. Bias or Conflict of Interest

The RIO will take reasonable steps to ensure that the members of the committee and experts have no bias or personal or professional conflict of interest with the respondent, informant, or the case in question. In making this determination, the RIO will consider whether the individual (or any members of his or her immediate family):

a. has any financial involvement with the respondent or informant;
b. has been a coauthor on a publication with the respondent or informant;
c. has been a collaborator or co-investigator with the respondent or informant;
d. has been a party to a research controversy with the respondent or informant;
e. has a supervisory or mentor relationship with the respondent or informant;
f. has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or informant; or
g. falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

4. Objection by Respondent

The RIO will notify the respondent of the proposed committee membership within 7 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 7 days, the RIO will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality

Members of the committee and experts will agree in writing to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, informant, witnesses, or anyone not authorized by the RIO to have knowledge of the inquiry. Administrative actions may be taken against any individual who breaches confidentiality.

6. Provision of Assistance

The RIO, in consultation with the institutional counsel, will provide staff assistance and guidance to the committee and the experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report.

G. Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, informant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose is **not** to determine whether research misconduct definitely occurred or who was responsible.

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 and time frame 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. If funding is involved, the inquiry committee will be provided with a copy of specific agency or ORI guidelines.

Note: Only 60 days is allowed from the 1st meeting of the Inquiry Committee to the decision by the DO of whether an investigation is needed. (See Appendix F for a suggested timeline.)

H. General Approaches to Conducting the Inquiry

During the inquiry, the committee will take the following steps:

1. Avoid Bias or Conflict of Interest

All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, informant, and witnesses.

2. Refer Other Issues

The RIO must be advised of any necessary interim actions to protect funds, human or animal subjects, or other steps required by regulation or policy. See Appendix B and C.

I. General Approaches to Conducting an Interview

1. Purpose of the Interview

The purpose of an interview at the inquiry stage is to allow each respondent, informant, or witness to tell his or her side of the story. The committee should not attempt to speculate about what happened or might have happened or put words in the witnesses' mouths. Also, the committee should not disclose information obtained from others interviewed unless this is necessary and can be done without identifying the source of the information.

2. Issues to Cover

Before an interview, the committee should provide each witness with a summary of the matters or issues intended to be covered at the interview. If the committee raises additional matters, the witness should be given an opportunity to supplement the record in writing or in another interview. The witness should be informed that his or her cooperation and truthful answers are expected.

3. Confrontation

Witnesses should not be told at this stage whether other testimony conflicts with theirs, although questions may be asked for purposes of clarifying the testimony. Avoid leading questions such as, "You must have made a mistake and thought it was actually this way, right?"

4. Using Experts

The committee may request that experts attend or participate in interviews to assist in its evaluation of the allegations and related issues. If the committee determines that such participation is not appropriate, it may ask an expert to prepare questions for the committee to use at the interview. Any expert retained to assist the committee may read the transcripts or summaries of the interviews.

5. Transcribing Interviews

Interviews with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or information. Changes to the transcript or summary will be made only to correct factual errors.

6. Confidentiality of Interviews

Witnesses should be advised that the proceedings are confidential and that they should not discuss the inquiry or their interview with anyone else other than their counsel or adviser. Witnesses may be asked to sign a confidentiality statement.

7. Access to Counsel

Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or witness in the case. However, the counsel or adviser may only advise the witness and may not participate directly in the interview. Witnesses will respond directly to the interview questions. The respondent or witness will be responsible for the selection and payment of counsel if obtained.

8. Order of Interviews

The inquiry committee should interview, if possible, the informant, key witnesses, and the respondent, in that order. Witnesses should be asked to provide, in advance if possible, any relevant evidence including their own notes, manuscripts, research activities records, or other documents that were not sequestered previously but are relevant to the allegation.

9. Interviewing the Informant

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

10. Interviewing the Respondent

The respondent should be asked to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of research judgement occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

11. Recording Admissions

If the respondent admits to the misconduct, the respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is a sufficient basis to proceed directly to an investigation. However, the admission may not be a sufficient basis for closing a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made, the RIO or institutional counsel may seek advice from ORI in determining whether there is a sufficient basis to close a case, after the admission is fully documented and all appropriate procedural steps are taken. If the case is closed, the report should

be forwarded to the Deciding Official with recommendations for appropriate institutional sanctions and then submitted to ORI for review.

12. Committee Deliberations

The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. **The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.**

Committee deliberations should never be held in the presence of the interviewee. During the interview, the committee members should not debate among themselves or with witnesses over possible research interpretations. These questions should be reserved for private discussions among the inquiry committee members and expert consultants.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; any funding or support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency. All relevant dates should be included in the report.

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

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

1. Confidentiality

The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report. For example, the RIO may request the recipient to sign a confidentiality statement and to come to the RIO’s office to review the draft report.

2. Receipt of Comments

Within 11 calendar days of their receipt of the draft report, the informant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the informant or respondent submits on the draft report will

become part of the final report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The RIO will notify both the respondent and the informant in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will complete the inquiry and submit its report in writing to the RIO no more than 54 calendar days following its first meeting, unless the RIO approves an extension for good cause. 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 will also be notified of the extension.

VII. Decision to Investigate

If the Deciding Official decides that an investigation will be conducted, and the project is funded by PHS, the RIO will notify ORI and will forward a copy of the final inquiry report and the institution's policies and procedures for conducting investigations to ORI. See Appendix C.

VIII. Referral to Other Agencies

Information obtained during the inquiry regarding allegations other than research misconduct involving support or funds should be referred to the responsible institutional officials or government agencies. See Appendix B.

IX. Conducting the Investigation

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope

beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human 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 immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry. See section V.C.

C. Notification of the Respondent

The RIO will notify the respondent as soon as reasonably possible after the determination is made to open an investigation. The notification should include: a copy of the inquiry report; the specific allegations; the sources of support or funding; the definition of research misconduct; the procedures to be followed in the investigation, including the appointment of the investigation committee and experts; the opportunity of the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report; the fact that ORI may perform an oversight review of the report regarding support or funding issues; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board (DAB) if there is an ORI finding of misconduct under the PHS definition.

D. Designation of a Committee to Conduct the Investigation

The RIO is responsible for designating a committee to conduct the investigation.

1. Investigation Committee

The RIO will normally appoint a committee of three or more persons to conduct the investigation, following the procedures set forth in section IX.E. and F.

2. Investigation Process

The investigation will normally follow each procedural step set forth below.

E. Appointment of the Investigation Committee

The RIO will use the following procedures to appoint an investigation committee:

1. Committee Membership

The RIO, in consultation with other institutional officials and personnel as appropriate, will appoint the investigation committee and the committee chair within 10 calendar days of the notification to the respondent or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

2. Experts

Experts may be appointed as noted in section V.F.2-4 (or carried over from the inquiry) to advise the committee on scientific or other issues.

3. Bias or Conflict of Interest

The RIO will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflict of interest with the respondent, informant, or the case in question. See section V.F.3.

4. Objection to Committee or Experts by Respondent

The RIO will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert based on bias or conflict of interest, the RIO will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality

Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, informant, witnesses, or anyone not authorized by the RIO to have knowledge of the investigation. Administrative actions may be taken against any individual who breaches confidentiality.

F. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry 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, informant, 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.

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 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 institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures, time frame, and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. If funding is involved, the investigation committee will be provided with a copy of specific agency or ORI guidelines.

Note: The final investigation report must be submitted to ORI within 120 days. (See Appendix F for a suggested timeline.)

G. Developing an Investigation Plan

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the informant, respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the investigative report.

H. General Approaches to Conducting the Investigation

During the investigation, the committee will take the following steps:

1. Avoid Bias or Conflict of Interest

All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, informant, and witnesses.

2. Refer Other Issues

The RIO must be advised of any necessary interim actions to protect funds, human or animal subjects, or other steps required by regulation or policy. (See Appendices A and B.)

3. Consult with the RIO and institutional counsel

The RIO and institutional counsel should be consulted throughout the investigation concerning compliance with UCA procedures and funding ORI and/or agency regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The RIO and Institutional Counsel will be present or available throughout the investigation to advise the committee.

I. Reviewing the Evidence

The investigation committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

J. Conducting Interviews

The investigation committee will conform to the following guidelines:

1. Conducting the Interviews

The investigation committee will conduct the interviews as described in section V.I.1-11, except that at the investigative stage interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.

2. Preparing for Interviews

The investigation committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

3. Objectivity

The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

4. Transcribing Interviews

Any interview with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

5. Recording Admissions

If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The committee should consult with the institutional counsel on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. The committee may ask the RIO or institutional counsel to consult with the specific funding agency or ORI when deciding whether an admission has adequately addressed all the relevant issues such that the investigation can be considered completed. The investigation should not be closed unless the respondent has been appropriately notified and given an opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the Deciding Official with recommendations for appropriate institutional actions and if funded, to the funding agency and or ORI for review.

K. Committee Deliberations

1. Burden and Standard of Proof

In reaching a conclusion on whether there was research misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence. See section III.G.

2. Definition of Research Misconduct

The committee will consider whether fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community occurred in proposing, conducting, or reporting research.

3. Sufficient Evidence

The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden of proving misconduct by a preponderance of the evidence. The committee will also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that research misconduct cannot be proven by a preponderance of the evidence.

X. The Investigation Report

A. Outline for an Investigation Report

The following annotated outline may prove useful in preparing the Investigation Report, except when special factors suggest a different approach.

1. Background

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

2. Allegations

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

3. Funding or Support

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

4. Institutional Inquiry: Process and Recommendations

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

5. Institutional Investigation: Process

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

6. Institutional Investigation: Analysis

   For each allegation:

Background

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

Analysis

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

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

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

Summarize each argument that the respondent raised in his or her defense against the research misconduct allegation and cite the source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

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

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

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

Conclusions

a. Findings of Misconduct or No Misconduct

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

A finding of research misconduct should be supported by a preponderance of the evidence.

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

If the investigation committee determines that the respondent committed research misconduct by seriously deviating from "other commonly accepted practices," the report should thoroughly document the commonly accepted practice of the relevant scientific community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publication, standards of the institution or relevant professional societies, State and Federal regulations, expert opinion, and other sources should be described and cited as the basis for the commonly accepted practice. The serious deviation should be described in detail, indicating why the alleged act was a serious deviation.

b. Misconduct under other University of Central Arkansas' Policies

The investigation committee may determine that an action that does not constitute research misconduct under the institution's definition is, nevertheless, misconduct under another of the institution's policies (*e.g.*, clinical protocol deviations or other violations of human subjects protection; documented animal welfare concerns; substandard data management practices; deficient mentoring of trainees). Any issue that the investigation committee determines to be misconduct solely under other policies of the institution's should be identified as such.

Recommended Institutional Actions

Based on its findings, the investigation committee should recommend administrative actions that it believes the institution should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, termination, etc. The institution should also identify any published research reports or other sources of research information (such as data bases) that should be retracted or corrected and take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

Attachments

Copies of all significant documentary evidence that is referenced in the report should be appended to the report, if possible (relevant notebook pages or other

records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and informant responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments."

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

B. Standard Format of the Investigation Report

The following outline should be used in preparing the Investigation Report, except when special factors suggest a different approach. The report should incorporate all of the elements described in section X.A.

1. Background
   - Chronology of events
   - Include public health issues

2. Allegations

3. Funding or Support or Application(s) (by allegation)

4. Institutional Inquiry: Process and Recommendations
   - Composition of committee
   - Individuals interviewed
   - Evidence sequestered and reviewed

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

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

7. Recommended Institutional Actions

8. Attachments

C. Documenting the Investigative File

1. Index of Evidence

The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research activities records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

2. Purpose of Documentation

The purpose of the documentation is to substantiate the investigation's findings.

3. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for three years after completion of the case to permit later assessment of the case. If funded, ORI, the funding agency or other authorized personnel will be given access to the records upon request.

D. Comments on the Draft Report

1. Respondent

The RIO will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 14 calendar days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Informant

The RIO will provide the informant, if he or she is identifiable, with those portions of the draft investigation report that address the informant's role and opinions in the investigation. The report should be modified, as appropriate, based on the informant's comments. The informant will review and comment on the draft report in the same 14 day time frame as the respondent.

3. Institutional Counsel

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

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and informant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to

sign a confidentiality statement and to come to his or her office to review the report.

E. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee. The Deciding Official's explanation should be consistent with the definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report.

When a final decision on the case has been reached, the RIO will notify both the respondent and the informant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding agencies.

F. Transmittal of the Final Investigation Report to ORI and/or a Funding Agency

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and informant's comments, to the ORI and/or the funding agency, through the RIO. All attachments to the final report should be submitted with the report. The final investigation report will be submitted to ORI and or the funding agency within 120 days of the first meeting of the investigation committee, unless the institution requests a written request for extension the funding agency and or ORI grants the extension.

G. Time Limit for Completing the Investigation Report

The final investigation report will be completed within 120 days of the first meeting of the investigation committee, unless the institution requests a written request for extension and ORI grants the extension. The RIO should maintain all other evidence and materials for possible funding agency and or ORI review.

XI. Institutional Administrative Actions

The institution will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where misconduct was found.

- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible termination of employment;

- restitution of funds as appropriate.

XII. Other Considerations

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

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

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

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and if PHS funded, 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 Deciding Official.

C. Protection of the Informant and Others

Regardless of whether the institution determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect informants 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 Deciding Official will determine, after consulting with the informant, what steps, if any, are needed to restore the position or reputation of the informant. The RIO is responsible for implementing any steps the Deciding Official approves. The RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the informant.

D. Allegations Not Made in Good Faith

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

E. Interim Administrative Actions

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

If the research is PHS supported, ORI regulations concerning review of the investigation report and follow-up shall be followed as described in Appendix D.

XIII. Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO of Committees. The RIO will keep the file for at least three years after completion of the case to permit later assessment of the case. ORI or Department of Health and Human Services (DHHS) authorized personnel will be given access to the records upon request.

XIV. Changes to Procedures

Changes in Federal Regulations (such as the definition of misconduct) or University policies could necessitate changes to this document. Appropriate notice of any such change shall be provided to the University community in writing.

Appendix A

Referral of Non-Research Misconduct Issues

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

1. HHS Criminal Violations

   Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General, HHS-OIG Hot line, P.O. Box 17303, Baltimore, MD 21203-7303, telephone (800) 368-5779. If the possible criminal violation is identical to the alleged scientific misconduct (*e.g.*, alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.

2. Violation of Human and Animal Subject Regulations

   Potential violation of human or animal subject regulations should be referred to the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20892-7507, telephone (301) 496-7005.

3. Violation of FDA Regulations

   Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, HFC-230 TWBK 715, Rockville, MD 20857, telephone (301) 827-0420.

4. Fiscal Irregularities

   Potential violations of cost principles or other fiscal irregularities should be referred as follows:

   a. For all NIH Agencies--Office of Management Assessment, NIH, Building 31, Room 1B05, Bethesda, MD 20892, telephone (301) 496-1361.

   b. For all other PHS Agencies--PHS Office of Grants and Contracts, 5600 Fishers Lane, Room 17A39, Rockville, MD 20857, telephone (301) 443-6630.

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

Appendix B

Requirements for Reporting to ORI

1. If PHS funding is involved, an institution's decision to initiate an investigation must be reported in writing to the director of ORI on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the definition of research misconduct, and the applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

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

3. 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.

4. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the RIO will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS 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.

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

    a. there is an immediate health hazard involved;
    b. there is an immediate need to protect funds or equipment;
    c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
    d. it is probable that the alleged incident is going to be reported publicly; or the allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
    e. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI and/or the funding agency within 24 hours of obtaining that information.

Note: If the research is funded or supported by a non-PHS agency, the agency should be contacted for its specific requirements for responding to allegations of research misconduct.

Appendix C

Oversight by ORI

A. Decision to Investigate

If the Deciding Official decides that an investigation will be conducted, the RIO will notify ORI and will forward a copy of the final inquiry report and the institution's policies and procedures for conducting investigations to ORI.

B. Decision Not to Investigate

If the Deciding Official decides not to proceed to an investigation and the inquiry was begun at the request of ORI, or if ORI requests a copy, the RIO will send a copy of the final inquiry report and the institutional decision to ORI. Otherwise, the case may be closed without notice to ORI.

C. Access to Evidence

If ORI is performing an oversight review of the institution's determination not to proceed to an investigation, the RIO, if so requested, will provide the inquiry report and the inquiry file including, but not limited to, sequestered evidence, analyses, and transcripts of interviews. The RIO will keep all records secure until ORI makes its final decision on its oversight of the institutional inquiry or investigation.

Appendix D

ORI Review of the Investigation Report and Follow-up

A. Purpose of ORI Review

ORI reviews the final investigation report, the supporting materials, and the Deciding Official's determinations to decide whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness, and competence. Based on its review, ORI may:

1. request additional information from the institution;

2. accept all the findings and conclusions of the report;

3. accept all or part of the factual findings of the report and make its own conclusions;

4. request additional investigation by the institution;

5. reject the report and conduct its own investigation;

6. impose administrative actions on the respondent beyond those recommended by the institution;

7. refer the case to the Division of Policy and Education, ORI, for a review of the institution's regulatory compliance; or

8. take any other action deemed to be in the public interest and within ORI's authority.

ORI will attempt to complete its review of the institution's report within 180 days of its receipt, except where additional follow up activities are required, such as an ORI request for additional information or analysis or where further investigation is necessary.

B. Cooperation with ORI Review

ORI is authorized by statute and PHS regulations to review institutional reports on allegations of research misconduct. In reviewing an institution's report, ORI may request additional information or other assistance from the RIO or other institutional officials. If the institutional official receiving the ORI request is unsure how to respond, he or she should consult with the RIO or institutional counsel. Institutional counsel may consult with ORI counsel prior to advising the institutional official on how to respond.

C. Request for Additional Documents and Information

The RIO will cooperate with any ORI request for additional documents and information by responding to all requests in a timely and responsive fashion. The RIO may consult with institutional counsel for advice as needed.

D. Notification of ORI Determination

1. ORI Concurrence

If ORI concurs with the institution's findings, ORI will notify the respondent and appropriate institutional officials in writing and will send the respondent and appropriate institutional official a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of research misconduct, the respondent will be notified of his or her opportunity to appeal to the DHHS Departmental Appeals Board (DAB). See 59 *Fed. Reg.* 29809 (1994).

2. ORI Nonconcurrence

If ORI does not concur with the institution's findings, ORI will notify the appropriate institutional official of the basis for that decision. If ORI does not concur with a finding of no misconduct, the institution may be requested to conduct a further investigation, either with the same or a different investigation committee, or ORI may conduct its own investigation. In the latter instance, ORI will notify the appropriate individuals of its investigation.

E. Cooperation in Appealed Cases

For cases in which ORI concurs with the institution's findings of scientific misconduct under the PHS definition or makes its own finding of scientific misconduct, ORI will request institutional employees to cooperate in presenting ORI findings of misconduct before the DAB if the respondent appeals the findings. Cooperation includes providing evidence, testimony, or any other information needed to assist in the preparation and presentation of ORI's case before the DAB. Institutional employees may consult with the RIO or institutional counsel in responding to ORI's request for cooperation.

Appendix E

PHS Regulation on Handling Allegations of Scientific Misconduct
(42 C.F.R. Part 50, Subpart A)

Part 50--Policies of General Applicability

Sec.
50.101 Applicability.
50.102 Definitions.
50.103 Assurance--Responsibilities of PHS Awardee and Applicant Institutions.
50.104 Reporting to the OSI.
50.105 Institutional compliance.

Subpart A--Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Authority: Sec. 493, Public Health Service Act, as amended, 99 Stat. 874-875 (42 U.S.C. 289b); Sec. 501(f), Public Health Service Act, as amended, 102 Stat. 4213 (42 U.S.C. 290aa(f)). Source: 54 FR 32449, Aug. 8, 1989, unless otherwise noted.

50.101 Applicability

This subpart applies to each entity which applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act. It requires each such entity to establish uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act. This subpart does not supersede and is not intended to set up an alternative to established procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

50.102 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended, (42 U.S.C. 201, et seq.).

Inquiry means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Institution means the public or private entity or organization (including federal, state, and other agencies) that is applying for financial assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or non-competing. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

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.

OSI means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

OSIR means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.

PHS means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

50.103 Assurance--Responsibilities of PHS awardee and applicant institutions.

(a) *Assurances*. Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant:

(1) Has established an administrative process, that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with it’s own administrative process and the requirements of this Subpart.

(b) *Annual Submission*. An applicant or recipient institution shall make an annual submission to the OSI as follows:

(1) The institution's assurance shall be submitted to the OSI, on a form prescribed by the Secretary, as soon as possible after November 8, 1989, but no later than January 1, 1990, and updated annually thereafter on a date specified by OSI. Copies of the form may be requested through the Director, OSI.

(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.

(c) *General Criteria*. In general, an applicant institution will be considered to be in compliance with its assurance if it:

(1) Establishes, keeps current, and upon request provides the OSIR, the OSI, and other authorized Departmental officials the policies and procedures required by this subpart.

(2) Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(4) Informs, in accordance with this subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

(d) *Inquiries, Investigations, and Reporting Specific Requirements.* Each applicant's policies and procedures must provide for:

(1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(4) Notifying the Director, OSI, in accordance with 50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in 50.104(b) exist.

(5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department's Office of Inspector General.

(6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

(7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key

aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

(8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(10) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purpose of the Federal financial assistance are carried out.

(12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(15) Notifying the OSI of the final outcome of the investigation.

50.104 Reporting to the OSI.

(a)(1) An institution's decision to initiate an investigation must be reported in writing to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

(2) An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

(3) Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under 50.103(d), a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

(4) The final report submitted to the OSI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and 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 taken by the institution.

(5) If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seem appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(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) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

Appendix F

SUGGESTED TIME LINES
All days are calendar days.

Suggested Time Line for Completing the Inquiry within 60 Days

Day 1	first meeting of the Inquiry Committee; charge to the committee given
Days 1-21	conduct the inquiry
Days 22-35	draft Inquiry Report written
Days 36-47	respondent and whistleblower comment on draft report
Days 48-53	comments incorporated into Inquiry Report
Day 54	Inquiry Report sent to Deciding Official
Days 54-60	Deciding Official makes determination whether there is sufficient basis for an investigation

Suggested Time Line for Completing the Investigation within 120 Days

Day 1	first meeting of the Investigation Committee; charge to the committee given
Days 1-69	conduct the investigation
Days 70-84	complete draft Investigation Report
Days 85-104	respondent and informant may view; complete the report attaching responses from respondent/informant if any
Day 105-119	report is given to Deciding Official for his/her determination, which is added to the report; this constitutes the Final Investigation Report
Day 120	Final Investigation Report is mailed to ORI and/or the funding agency (if externally funded)