

# University Policy for Responding to Allegations of Research Misconduct

## A. Introduction

### 1. General Policy

Research misconduct will not be tolerated or accepted at Case Western Reserve University. Scientific integrity and ethics are highly valued and expected from all members of the University community. While ensuring compliance, the University will make all efforts to protect the rights and reputations of all individuals including the respondent and good faith complainant.

The University will educate researchers and staff members on policies and the importance of compliance. Preventative measures are by far the most productive and least damaging to all involved. Our goal is to initiate department-level discussions among students, faculty, and staff researchers to examine the contemporary stresses felt on academic research ethics, and to consider ways to deal with those stresses.

The University's basic procedural approach to handling allegations of research misconduct is to investigate as soon as misconduct is suspected, inform and cooperate with the Office of Research Integrity (ORI), and to follow the proceeding policies.

### 2. Scope

This policy and the associated procedures apply to all individuals at Case Western Reserve University engaged in any research whether it is supported by the U.S. Public Health Service (PHS) or not. The PHS regulation, 42 Code of Federal Regulations (CFR) Part 93, applies to any research, research-training or research-related grant or cooperative agreement with PHS. This University policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at Case Western Reserve University. While the University's authority to investigate, to compel cooperation, and to impose sanctions against those who are not members of the University Community is limited, the University will nonetheless investigate all allegations of misconduct involving research.

The policy and associated procedures will normally be followed when an allegation of possible research misconduct is received by a University official. Particular circumstances in an individual case may dictate variation from the normal procedure, when such variations are deemed to be in the best interests of Case Western Reserve University and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation

## **B. Definitions**

1. *Allegation* means any written or oral statement or other indication of possible research misconduct made to a University or HHS official where the alleged misconduct occurred within six years of the date the University received the allegation.
2. *Complainant* means a person who makes an allegation of research misconduct.
3. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
4. *Deciding Official* means the University official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment.
5. *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 knowing or reckless disregard for the information that would negate the allegation.
6. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
7. *Investigation* means the formal examination and evaluation of all relevant facts to determine whether misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.
8. *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 research misconduct and research integrity activities of the U.S. Public Health Service.
9. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
10. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Part 93, "Public Health Service Policies on Research Misconduct."
11. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefore.
12. *Research Integrity Officer* means the University official responsible for assessing allegations of research misconduct and determining whether such allegations warrant

inquiries and for overseeing inquiries and investigations.

13. *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.
14. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
15. *Retaliation* means any action that adversely affects the employment or other institutional 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
16. *Research Misconduct* means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit. Research misconduct does not include honest error or differences in opinion.

A finding of research misconduct requires that 1) there be a significant departure from accepted practices of the relevant research community, 2) the misconduct be committed intentionally, knowingly or recklessly; and 3) the allegation be proven by a preponderance of the evidence.

## **C. Rights and Responsibilities**

### **1. Research Integrity Officer**

The Research Integrity Officer will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be a University official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and shall take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable. He/she shall select those conducting the inquiry or investigation on the basis of scientific expertise that is pertinent to the matter and, prior to selection, shall screen them for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection.

To the extent allowed by law, the Research Integrity Officer shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

The Research Integrity Officer will assist inquiry and investigation committees and all University personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

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

## 2. Complainant

The complainant will ordinarily have an opportunity to be interviewed by the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the complainant may be able to provide pertinent information on any portions of the draft report; these portions may be given to the complainant for comment.

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

### 3. Respondent

The respondent will be informed in writing of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advisor of choice. Advisors, however, may only consult with the respondent. They may not address the committee, ask questions of the committee, or participate in the interviews.

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

### 4. Deciding Official

The Vice President for Research and Technology Management (or in his/her absence the Provost) as the Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

## **D. General Policies and Principles**

### 1. Responsibility to Report Misconduct

All employees or individuals associated with Case Western Reserve University should report observed, suspected, or apparent misconduct in research to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

### 2. Protecting the Complainant

The Research Integrity Officer will monitor the treatment of individuals who bring

allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will attempt to ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees or those affiliated with the University or a PHS grant should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

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

### 3. Protecting the Respondent

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

University employees accused of research misconduct may consult with an advisor (who is not a principal or witness in the case) to seek advice and may bring the advisor to interviews or meetings on the case. However, the advisor may only consult with the respondent. Advisors may not address the committee, ask questions of the committee, or participate in the interview.

### 4. Cooperation with Inquiries and Investigations

University employees and those working on PHS grants will cooperate with the Research Integrity Officer 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 Research Integrity Officer or other University officials on misconduct allegations.

### 5. Preliminary Assessment of Allegations

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the Research Integrity Officer shall assess the allegation to determine if: (1) it meets the definition of research misconduct in 42 CFR Section 93.103; (2) it involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b) or other non-PHS support; and, (3) the allegation is sufficiently

credible and specific so that potential evidence of research misconduct may be identified. This assessment will be presented in writing to the Deciding Official for concurrence before the Research Integrity Officer either closes the matter or proceeds to inquiry. All parties will be notified in writing if the matter is closed after the preliminary assessment.

## **E. Conducting the Inquiry**

### **1. Initiation and Purpose of the Inquiry**

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up and falls under the PHS definition of research misconduct, he or she will initiate the inquiry process whether it involves PHS support or not. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry will be set forth in an inquiry report.

### **2. Sequestration of the Research Records**

After determining that an allegation falls within the definition of misconduct in research, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

The Research Integrity Officer shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

(1) **Either before or when the Research Integrity Officer notifies the respondent of the allegation**, the Research Integrity Officer shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

(2) Where appropriate, give the respondent copies of, or as reasonable, supervised access to the research records.

(3) Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct

proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (1) above.

### 3. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other University officials as appropriate, will appoint an inquiry committee and committee chair. The inquiry committee should consist of 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 the University.

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

### 4. Charge to the Committee and the First Meeting

The Research Integrity Officer 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, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

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

### 5. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent and key witnesses as well as review relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and the University Attorney's office, 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.

## **F. The Inquiry Report**

### **1. Elements of the Inquiry Report**

The written inquiry report shall contain the following information: (1) The name and position of the respondent(s); (2) A description of the allegations of research misconduct; (3) The PHS support involved, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support or other non-PHS support; (4) The basis for recommending that the alleged actions warrant an investigation; and (5) Any comments on the report by the respondent or the complainant. The report should also include recommendations on whether any other actions should be taken if an investigation is not recommended. The University Attorney's office will review the report for legal sufficiency.

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

The Research Integrity Officer will provide the respondent with a copy of the inquiry report for comment and rebuttal, along with a copy of this policy. The Research Integrity Officer may provide the complainant, if he or she is identifiable; with a summary of the inquiry findings that addresses the complainant's role and opinions in the investigation.

#### **a. Confidentiality**

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the report.

#### **b. Receipt of Comments**

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

### **3. Inquiry Decision and Notification**

#### **a. Decision by Deciding Official**

The Research Integrity Officer 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. The determination is ordinarily made within 60 days of

the first meeting of the inquiry committee, unless circumstances warrant a longer period. The reasons for exceeding the 60-day period shall be documented in the inquiry record.

b. Notification

The Research Integrity Officer will ordinarily notify both the respondent and the complainant 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 Research Integrity Officer will also notify all appropriate University officials of the Deciding Official's decision.

4. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, unless the Research Integrity Officer approves an extension because circumstances warrant a longer period. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records. The respondent also may be notified of the extension.

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of the institution finding that an investigation is warranted), the Research Integrity Officer shall provide ORI with the written finding by and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a). Upon a request from ORI he/she shall promptly send them: (1) a copy of institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider. Inquiry reports of allegations that do not involve PHS support in accordance with the definition of research misconduct will not be forwarded to ORI, but will otherwise be in accordance with this policy.

**G. Conducting the Investigation**

1. 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.

2. Sequestration of the Research Records

The Research Integrity Officer 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 University'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.

3. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other University officials as appropriate, will appoint an investigation committee and the committee chair as soon as practicable after the respondent has been notified that an investigation is planned. 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 University. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the respondent of the proposed committee membership. If the respondent submits a written objection to any appointed member of the investigation committee, the Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute.

4. Charge to the Committee and the First Meeting

a. Charge to the Committee

The Research Integrity Officer 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, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

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 Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

b. The First Meeting

The Research Integrity Officer, with the University Attorney's office, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

5. Investigation Process

In conducting all investigations, the University shall: (1) Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations; (2) Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation; (3) Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion; and (4) Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310

The respondent will be notified sufficiently in advance of the scheduling of his/her interview so that the respondent may prepare for the interview and arrange for the attendance of an advisor, if the respondent wishes.

**H. The Investigation Report**

1. Elements of the Investigation Report

The Research Integrity Officer, in conjunction with the Investigation Committee, shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312. The final investigation report shall:

(1) Describe the nature of the allegations of research misconduct;

(2) Describe and document the PHS support (if applicable), including, for example any

grant numbers, grant applications, contracts, and publications listing PHS support;

(3) Describe the specific allegations of research misconduct considered in the investigation;

(4) Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI;

(5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. **The report should also describe any relevant records and evidence not taken into custody and explain why.**

(6) Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, (i) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard, (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations, (iii) identify the specific PHS support or other support; (iv) identify any publications that need correction or retraction; (v) identify the person(s) responsible for the misconduct, and (vi) list any current support or known applications or proposals for support that the respondent(s) has pending with non-PHS Federal agencies; and

(7) Include and consider any comments made by the respondent and complainant on the draft investigation report.

The University shall maintain and provide to ORI upon request all relevant research records and records of its research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

## 2. Comments on the Draft Report

### a. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent that any comments must be submitted within 30 days of the date on which he/she received the draft report.. The respondent's comments will be attached to the final report and are considered in the final investigation report.

### b. Complainant

The Research Integrity Officer will provide the complainant; if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report may be modified,

as appropriate, based on the complainant's comments.

c. Review by University Attorney's Office

The draft investigation report will be transmitted to the University Attorney's office for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

d. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the Research Integrity Officer 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 Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

3. University 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 University actions. A preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. 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 in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, the University'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 for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the complainant in writing of the decision. 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

4. Transmittal of the Final Investigation Report

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 complainant's comments, to the Deciding Official, through the Research Integrity Officer.

5. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation ordinarily beginning with the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI. If the University will not be able to complete the investigation in 120 days, it will submit to ORI a written request for an extension and an explanation for the need for an extension.

**I. Requirements for Reporting to ORI**

1. The University shall promptly provide to ORI after the investigation: (1) A copy of the investigation report, all attachments, and any appeals; (2) A statement of whether the institution found research misconduct and, if so, who committed it; (3) A statement of whether the institution accepts the findings in the investigation report; and (4) A description of any pending or completed administrative actions against the respondent. *(Only actions involving respondents who receive funding from PHS will be reported to ORI.)*
2. If the University plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.
3. If the University determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer 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 Research Integrity Officer will file periodic progress reports as requested by the ORI.
4. When the case involves PHS funds, the University 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. At any time during a research misconduct proceeding, the University shall notify ORI immediately if it has reason to believe that any of the following conditions exist:
  - (1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
  - (2) HHS resources or interests are threatened.

- (3) Research activities should be suspended.
- (4) There is a reasonable indication of violations of civil or criminal law.
- (5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- (6) The University believes the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (7) The University believes the research community or public should be informed.

#### **J. Institutional Administrative Actions**

The University will cooperate with and assist ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS.

The University will also 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 Research Integrity Officer. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- restitution of funds as appropriate.

The University will report to ORI any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

#### **K. Other Considerations**

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

The termination of the respondent's employment with the University, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, ordinarily 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 ordinarily will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

2. Restoration of the Respondent's Reputation

If the University finds no misconduct or that the allegation of misconduct cannot be substantiated and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer 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.

3. Protection of the Complainant and Others

Regardless of whether the University or ORI determines that research misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Research Integrity Officer will determine, after consulting with the complainant, what steps, if any, are needed to protect or restore the position or reputation of the complainant. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

4. Allegations Not Made in Good Faith

If relevant, the Inquiry or Investigation Committee will determine whether the complainant's allegations of research misconduct were not made in good faith and will include such determination in its respective report. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the complainant.

5. Interim Administrative Actions

At any time during a research misconduct proceeding, the University shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

#### **L. Record Retention**

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees.

The University shall cooperate fully and on a continuing basis with ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under the University's control or custody, or in the possession of, or accessible to, all persons that are subject to the University's authority.

The University shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless the University has transferred custody of the records and evidence to HHS, or ORI has advised the University that it no longer need to retain the records.