

Policy: **ALLEGED MISCONDUCT RESEARCH AND CREATIVE ACTIVITIES**

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Approved By: George M. Dennison, President

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Note: This document can be made available in an alternative format upon request.

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Policy

for Responding to Allegations of Misconduct

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## Preface

This document was prepared so that The University of Montana would comply with federal requirements for institutions receiving federal research funds. The requirements state that such institutions shall have a policy on "Responding to Allegations of Scientific Misconduct." As such, the word "science" and "research" appear in the text of this document to comply with the original intent. However, a decision was made by The Office of the Vice President for Research to broaden the scope so that the policy applies to misconduct in all "creative activities." Thus, this document should bring the University into compliance with policy requirements from other federal departments and agencies, which may institute "misconduct" policies. In the text, a few examples of scientific misconduct are presented; however, more specifics are not given. The possibilities would be extensive if all types of creative activities were considered. Therefore, in defining specific cases of misconduct, it ultimately will be the responsibility of the (peer) inquiry committee to interpret the general misconduct statement in Section II.O. Finally, it is not the intent or purpose of this document to cover the wide range of "misconduct behaviors" that are prohibited by other policies or laws.

## I. Introduction\*

### A. Policy

It is the intent and purpose of this policy to establish an administrative process for dealing with misconduct in research and creative activities, or allegations thereof, so that the integrity of research conducted or services provided at The University of Montana is maintained, and to provide assurance to federal agencies that The University of Montana is in compliance with federal regulations for institutional oversight of misconduct.

### B. Scope

This policy and associated procedures apply to all individuals at The University of Montana engaged in research or other creative activities whether or not they are supported by or for which support is requested from a federal agency.

The PHS regulation at 42 C.F.R. Part 50, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. The National Science Foundation regulation is at 45 C.F.R. 689.

### C. Application

This policy applies to any persons paid by, under the control of, or affiliated with the institution, such as faculty members, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at The University of Montana.

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\*Sections that are based on requirements of the PHS regulations codified at 42 C.F.R. Part 50, Subpart A have endnotes that indicate the applicable section number, e.g., 42 C.F.R. 50.103(d)(1).

The policy and associated procedures will normally be followed when an allegation of possible misconduct is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of The University of Montana and the involved federal funding agency, if any. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Vice President for Research and Development of The University of Montana.

## II. Definitions

- A. *Allegation* means any written or oral statement or other indication of possible misconduct made to an institutional official.
- B. *Conflict of Interest* means the 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 Provost, The University of Montana who, as the institutional official, makes final determinations on allegations of scientific 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.**
- D. *Good Faith Allegation* means an allegation made with the honest belief that scientific or other 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; any such allegation may subject the person making it to adverse employment and private legal action.
- E. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation of misconduct warrants an investigation.<sup>1</sup>
- F. *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.<sup>2</sup>
- G. *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 misconduct and research integrity activities of the U.S. Public Health Service.

In the case of the National Science Foundation (NSF), the appropriate office is the Office of the Inspector General. In the case of other federal agencies, an appropriate office of the involved federal agency will be identified.

- H. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- I. *PHS Regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of 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."
- J. *Federal Support* means federal grants, contracts, or cooperative agreements or applications therefor.
- K. *Research Integrity Officer* means the institutional official responsible for assessing allegations of misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
- L. *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 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.
- M. *Respondent* means the person against whom an allegation of 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.
- N. *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 misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.
- O. *Misconduct or Misconduct in Science* means professional misconduct or other practices that seriously deviate from those commonly accepted

within the research or creative activities community for proposing, conducting, or reporting research and other creative activities. It does not include honest error or honest differences in interpretations or judgments of data.

P. *Whistleblower* means a person who makes an allegation of misconduct. For purposes of clarification, the definitions are expanded as follows:\*

1. Misconduct in Research or Creative Activities

This is a significant misbehavior that improperly acquires the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record\*\* or compromising the integrity of scientific and other creative activity practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:

- a) Misappropriation: An investigator or reviewer shall not intentionally or recklessly;
  - 1) plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as the presenter's own, without attribution for the medium of presentations; or
  - 2) make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

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\* Integrity and Misconduct in Research, a Report of the Commission on Research Integrity to the Secretary of Health and Human Services, 1995.

\*\* The record encompasses any documentation or presentation of research, oral or written, published or unpublished.

- b) Interference: An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.
- c) Misrepresentation: An investigator or reviewer shall not, with intent to deceive or in reckless disregard for the truth:
  - 1) state or present a material or significant falsehood; or
  - 2) omit a fact so that what is stated or presented as a whole, states or presents a material or significant falsehood. Free scientific inquiry naturally includes proposing hypotheses that may ultimately prove to be false, offering interpretations of data that conflict with other interpretations, and making scientific observations and analyses that may prove to be in error. The sanctionable acts defined and elaborated here are not intended to limit or define comprehensively the oversight role of academic and research institutions.

## 2. Other Forms of Professional Misconduct

- a) Obstruction of Investigations of Research Misconduct  
The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential leads to witnesses or



evidence before, during, or after the commencement of any formal or informal proceeding.

- b) **Noncompliance with Research Regulations**  
Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

### 3. Standard of Proof

The standard of proof for misconduct is that the clear and convincing evidence must support the conclusion that the acts or practices in question were serious deviations from those commonly employed in the United States for proposing, conducting or reporting research and other creative activities. In determining whether or not misconduct occurred, both action and intent will be considered.

## **III. Rights and Responsibilities**

### A. Research Integrity Officer

The Vice President for Research and Development will serve as the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer must be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research or participate in other creative activities, 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 ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will make every attempt to ensure that confidentiality is maintained.

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

The Research Integrity Officer will report to ORI or the office identified by the involved federal agency as required by regulation and keep that office informed of any developments during the course of the inquiry or investigation that may affect current or potential federal funding for the individual(s) under investigation or that the involved federal agency needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.<sup>4</sup>

#### B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to the whistleblower's 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 whistleblower may be able to provide pertinent information on any portions of the draft report, these portions may be given to the whistleblower for comment.

The whistleblower must have credibility, no conflict of interest, be accountable, and is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

#### C. Respondent

The respondent will be informed 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 advice of the respondent's counsel.

The respondent is responsible for maintaining confidentiality and cooperation during inquiry or investigation. If the respondent is not found guilty of misconduct, the respondent has the right to receive institutional assistance in restoring his or her reputation.<sup>5</sup>

#### D. Deciding Official

The Deciding Official (Provost) will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions (see Section X).

#### **IV. General Policies and Principles**

##### **A. Responsibility to Report Misconduct**

All employees or individuals associated with The University of Montana should report observed or suspected misconduct in science and creative activities to the Research Integrity Officer. An individual, unsure whether a suspected incident falls within the definition of scientific misconduct, may call the Research Integrity Officer at (406) 243-6670 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of 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 confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations, which may be made orally and anonymously.

##### **B. Protecting the Whistleblower**

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 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 should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

The institution will protect the privacy of those who report misconduct in good faith<sup>6</sup> to the maximum extent possible. For example, if the whistleblower requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry, within applicable policies, regulations, and state and local laws.

The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may be lost. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.<sup>7</sup>

#### C. Protecting the Respondent

The respondent will be provided with written notice of allegations within 5 days of their receipt. Inquiries and investigations will be conducted in a manner that will protect the respondent and the respondent's professional reputation, ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.<sup>8</sup>

Institutional employees accused of misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice.

#### D. Cooperation with Inquiries and Investigations

Institutional employees 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 institutional officials on misconduct allegations.

#### E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether federal support or federal applications for funding are involved, and whether the allegation falls under the federal definition of misconduct.

## V. Conducting the Inquiry

### A. 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, involves federal support, or falls under the PHS definition of misconduct, the Research Integrity Officer will immediately initiate the inquiry process. 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, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible 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. Sequestration of the Research Records and Other Material Information

After determining that an allegation falls within the definition of misconduct, the Research Integrity Officer must ensure that all relevant original research records and materials relevant to the allegation are immediately secured for the duration of the process; access to the records will only be made through the Research Integrity Officer. The Research Integrity Officer may consult with ORI or appropriate office of the involved federal agency for advice and assistance in this regard. At any time during the inquiry, Research Integrity Officer or Inquiry Committee members may sequester more relevant records as necessary.

### C. Appointment of the Inquiry Committee

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

The Research Integrity Officer will notify the respondent of the proposed committee membership in 10 days. If the respondent submits a written objection stating a valid 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.

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

The Research Integrity Officer will prepare a charge for the inquiry committee that:

- a) describes the allegations,
- b) any related issues identified during the allegation assessment, and
- c) states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible misconduct to warrant an investigation as required by the federal regulation. The purpose is not to determine whether 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 institutional legal counsel, or the legal counsel's designee, will be available throughout the inquiry to advise the committee as needed.

#### E. Inquiry Process

The inquiry committee may interview the whistleblower, the respondent, and key witnesses as well as examining 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 institutional legal counsel, the committee members will decide whether there is sufficient evidence of possible misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

## **VI. The Inquiry Report**

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

A written inquiry report must be prepared that includes the name and title of the committee members and experts, if any; allegations; federal source of support; summary of the inquiry process used; list of the research records reviewed; summaries of any interviews; description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; 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 legal counsel will review the report for legal sufficiency.

### **B. Comments on the Draft Report by the Respondent and the Whistleblower**

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower with either portions or a summary of the draft inquiry report that address the whistleblower's role and opinions in the investigation.

#### **1. Confidentiality**

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

#### **2. Receipt of Comments**

Within 14 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record.<sup>9</sup> Based on the comments, the inquiry committee may revise the report as appropriate.

### **C. Inquiry Decision and Notification**

#### **1. 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 misconduct to justify conducting an investigation. The inquiry is

completed when the Deciding Official makes this determination, which will be made within 30 days of the first meeting of the inquiry committee. Any extension of this period must be made by mutual consent of the Research Integrity Officer and the respondent and will be based on good cause and recorded in the inquiry file.

## 2. Notification

The Research Integrity Officer will notify both the respondent and whistleblower 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 institutional officials of the Deciding Official's decision. If an investigation is warranted or if it is determined that any conditions in 42 C.F.R. 50.104(b) exist, the Research Integrity Officer must notify appropriate federal offices as stipulated in 42 C.F.R. 50.103(d)(4).

## D. 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 30 calendar days following its first meeting,<sup>10</sup> unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and report.<sup>11</sup> The respondent also will be notified of the extension.

## **VII. 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 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 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. If additional allegations arise at this point, they will revert to an inquiry phase and be considered as described in Section V above.

## C. Appointment of the Investigation Committee

An investigation must be initiated within 30 days of a completed inquiry and completed within 90 days. The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have 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.<sup>12</sup> These individuals may be scientists, administrators, subject matter experts, lawyers, consultants, 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.

The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection stating reason to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

## D. Charge to the Investigation Committee and the First Meeting

### 1. 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 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, whistleblower, and key witnesses to determine whether, based on clear and convincing evidence, 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.

## 2. The First Meeting

The Research Integrity Officer, with the assistance of institutional legal counsel or the legal counsel's designee, 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 federal funding is involved, the appropriate federal regulation.

## E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.<sup>13</sup>

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.<sup>14</sup> Whenever possible, the committee should interview the whistleblower(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations.<sup>15</sup> Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.<sup>16</sup>

## **VIII. The Investigation Report**

### **A. Elements of the Investigation Report**

Following the procedure outlined below, a final written report will be prepared and submitted to the Research Integrity Officer and, if federal funds are involved, to ORI or appropriate office of the involved federal agency must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.<sup>17</sup>

### **B. Comments on the Draft Report**

#### **1. Respondent**

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 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. Whistleblower**

The Research Integrity Officer will provide the whistleblower with those portions of the draft investigation report that address the whistleblower's role and statements in the investigation. The whistleblower will be allowed 14 days to respond to the report, particularly noting any inaccuracies as they relate to the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

#### **3. Institutional Legal Counsel**

The draft investigation report will be transmitted to the institutional legal counsel, or the legal counsel's designee, 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 whistleblower, 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 the Research Integrity Officer's office to review the report.

#### C. Institutional Review and Decision

Based on clear and convincing 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 in the institution's letter transmitting the report to ORI or the office of the involved federal agency. The Deciding Official's explanation should be consistent with the PHS definition of 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 for purposes of review by ORI or the involved federal agency if federal funds were involved.

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

#### D. 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 whistleblower's comments, to the Deciding Official, through the Research Integrity Officer.

#### E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 90 days of its initiation,<sup>18</sup> with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI or appropriate office of the involved federal agency.<sup>19</sup>

### **IX. Requirements for Reporting to ORI**

#### A. Initiation

An institution's decision to initiate an investigation (as defined in Section II involving federal funds must be reported in writing to the Director, ORI, or appropriate officer of the involved federal agency on or before the date the investigation begins.<sup>20</sup> 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 PHS definition of misconduct, and the federal applications or grant number(s) involved.<sup>21</sup> ORI or office of the involved federal agency must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.<sup>22</sup> Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI or office of the involved federal agency.

## B. Termination

If an institution 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 or the appropriate office of involved federal agency, including a description of the reasons for the proposed termination.<sup>23</sup>

## C. Non-completion

If the institution determines that it will not be able to complete the investigation in 90 days, the Research Integrity Officer will submit to ORI or appropriate office of the involved federal agency, 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<sup>24</sup> reports as requested by the ORI<sup>24</sup> or office of the involved federal agency.

## D. Involvement of Federal Funding

When federal funding or applications for funding are involved and an admission of misconduct is made, the Research Integrity Officer will contact ORI or the appropriate office of the involved federal agency 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 federal funds, the institution cannot accept an admission of misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI<sup>25</sup> or the appropriate office of the involved federal agency.

## E. Duties of Research Integrity Officer

The Research Integrity Officer will notify ORI or the appropriate office of the involved federal agency at any stage of the inquiry or investigation if:

1. there is an immediate health hazard involved;<sup>26</sup>
2. there is an immediate need to protect Federal funds or equipment;<sup>27</sup>
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 such individual's co-investigators and associates, if any;<sup>28</sup>
4. it is probable that the alleged incident is going to be reported publicly;<sup>29</sup> or
5. the allegation involves a public health sensitive issue, e.g., a clinical trial; or
6. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI or appropriate office

of the involved federal agency within 24 hours of obtaining that information.<sup>30</sup>

## **X. Institutional Administrative Actions**

The University of Montana will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.<sup>31</sup>

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, after consultation with the Research Integrity Officer, the case file will be turned over to the University President who will decide on the appropriate actions to be taken. The actions may include:

withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific 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.

## **XI. 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 misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign from the University 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 ORI or appropriate office of the involved federal agency concurs, after consulting with the respondent, the Research Integrity Officer will undertake concerted 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 misconduct was previously publicized, or expunging all reference to the scientific 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 Whistleblower and Otherwise<sup>32</sup>

Regardless of whether the institution, ORI, or the appropriate office of the involved federal agency determines that misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers who made allegations of 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 whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

## D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine, after consulting with the Research Integrity Officer and members of the Investigation Committee, whether the whistleblower's allegations of 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 whistleblower. In addition allegations not made in good faith may subject the whistleblower to external legal action.

## E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out.<sup>33</sup>



## **XII. 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 Research Integrity Officer will keep the file for three years after completion of the case to permit later assessment of the case. ORI, the office of the involved federal agency, or other authorized federal personnel will be given access to the records upon request.<sup>34</sup>

## **XIII. Training in Research Ethics**

Through the Practical Ethics Center, The University of Montana-Missoula offers an 18 hour seminar series on Research Ethics. Graduate students, post-doctoral fellows and faculty are encouraged to take advantage of this course. If formal training in ethics is mandated for institutions applying for or receiving federal grants, contracts, or cooperative agreements, formal training Research Ethics will be required of principal investigators and students supported by these funds and an assurance of compliance will be included in a checklist that accompanies every research or training grant application.

**NOTES:**

1. 42 C.F.R. 50.102.
2. 42 C.F.R. 50.102.
3. 42 C.F.R. 50.102.
4. 42 C.F.R. 50.103(d) (12).
5. 42 C.F.R. 50.103(d) (13).
6. 42 C.F.R. 50.103(d) (2).
7. 42 C.F.R. 50.103(d) (13).
8. 42 C.F.R. 50.103(d) (3).
9. 42 C.F.R. 50.103(d) (1).
10. 42 C.F.R. 50.103(d) (1).
11. 42 C.F.R. 50.103(d) (1).
12. 42 C.F.R. 50.103(d) (8).
13. 42 C.F.R. 50.103(d)(7).
14. 42 C.F.R. 50.103(d) (7).
15. 42 C.F.R. 50.103(d) (7).
16. 42 C.F.R. 50.103(d) (7).
17. 42 C.F.R. 50.104(a)(4); 42 C.F.R.; 50.103(d)(15).
18. 42 C.F.R. 50.104(a) (2).
19. 42 C.F.R. 50.104(a) (2).
20. 42 C.F.R. 50.104(a) (1).
21. 42 C.F.R. 50.104(a) (1).
22. 42 C.F.R. 50.103(d) (15).
23. 42 C.F.R. 50.104(a)(3).
24. 42 C.F.R. 50.104(a) (5).
25. 42 C.F.R. 50.104(a) (3).
26. 42 C.F.R. 50.104(b) (1).
27. 42 C.F.R. 50.104(b) (2).
28. 42 C.F.R. 50.104(b) (3).
29. 42 C.F.R. 50.104(b) (4).
30. 42 C.F.R. 50.104(b)(5).
31. 42 C.F.R. 50.103(d) (14).
32. 42 C.F.R. 50.103(d) (14).
33. 42 C.F.R. 50.103(d) (11).
34. 42 C.F.R. 50.103(d) (10).