

UNIVERSITY OF DELAWARE
POLICY FOR
RESPONDING TO ALLEGATIONS OF
RESEARCH MISCONDUCT

University of Delaware
Research Office
124 HULLIHEN HALL ♦ NEWARK, DE 19716
Phone: (302) 831-4007 ♦ Fax: (302) 831-8620

University of Delaware
Policy for Responding to
Allegations of Research Misconduct

Table of Contents

I.	Introduction.....	1
	A. General Policy	1
	B. Scope.....	1
II.	Definitions	1
III.	Rights and Responsibilities.....	3
	A. Research Integrity Officer	3
	B. Complainant	4
	C. Respondent.....	4
	D. Deciding Official.....	5
IV.	General Policies and Principles.....	6
	A. Responsibility to Report Misconduct	6
	B. Protecting the Complainant, Witnesses and Committee Members	6
	C. Protecting the Respondent	6
	D. Cooperation with Inquiries and Investigations.....	7
V.	Conducting the Assessment and Inquiry	7
	A. Assessment of Allegations	7
	B. Initiation and Purpose of the Inquiry	7
	C. Notice to Respondent; Sequestration of Research Records	7
	D. Appointment of the Inquiry Committee.....	8
	E. Charge to the Committee and First Meeting.....	8
	F. Inquiry Process	9
	G. Time for Completion	9
VI.	The Inquiry Report.....	9
	A. Elements of the Inquiry report	9
	B. Comments on the Draft Report by the Respondent and the Complainant.....	9
	C. Institutional Decision and Notification.....	10
	D. Time Limit for Completing the Inquiry Report	10

VII.	Conducting the Investigation	11
	A. Initiation and Purpose of the Investigation	11
	B. Notifying the Cognizant Agency; Sequestration of the Research Records	11
	C. Appointment of the Investigation Committee.....	11
	D. Charge to the Committee and the First Meeting	12
	E. Investigation Process	12
VIII.	The Investigation Report	13
	A. Elements of the Investigation Report	13
	B. Comments on the Draft Report	13
	C. Institutional Review and Decision.....	14
	D. Transmittal of the Final Investigation Report to the Cognizant Agency	14
	E. Time Limit for Completing the Investigation	14
IX.	Requirements for Reporting.....	15
X.	Institutional Administrative Actions	16
XI.	Other Considerations	16
	A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation.....	16
	B. Restoration of the Respondent’s Reputation.....	16
	C. Protection of the Complainant and Others.....	19
	D. Allegations Not Made in Good Faith	17
	E. Interim Administrative Actions.....	17
XII.	Records Retention	17

I. Introduction

A. General Policy

The University of Delaware has the ethical responsibility to prevent misconduct in research and the legal responsibility to inquire into all allegations of research misconduct and to report and investigate all instances where a reasonable presumption of misconduct is established by inquiry.

The University, the State, suppliers of grant accounts, clients of consultation services, and the public all have the right to expect and demand unbiased and factual information from University personnel. In the long run, University personnel benefit individually and collectively from the maintenance of high ethical standards.

An atmosphere of intellectual honesty enhances the research process and need not inhibit productivity and creativity. Establishing and maintaining such an atmosphere is a responsibility that must be accepted by all University personnel.

B. Scope

This policy and the associated procedures apply to all individuals at the University of Delaware engaged in research. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the University.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in research 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 Delaware and the cognizant funding agency. 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 Provost for Research.

II. Definitions

- A. *Allegation* means any written or oral statement or other communication made to an institutional official which indicates possible research misconduct.
- B. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- C. *Deciding Official* means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The 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 research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- E. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
- F. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.
- G. *Research Integrity Officer* means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
- H. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments or in reporting research results.
- I. *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.
- J. *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.
- K. *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.
- L. *Complainant* means a person who makes an allegation of research misconduct.

III. Rights and Responsibilities

A. Research Integrity Officer

The Provost will appoint the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will 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, those who are accused of misconduct, and those who report apparent misconduct in good faith. The Research Integrity Officer will have the following responsibilities and duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. Of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has any unresolved personal, professional, or financial interest and take

appropriate action, including recusal, to ensure no person with such conflict is involved in the research misconduct proceeding;

- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

C. Respondent

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

- A good faith effort from the Research Integrity Officer to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within thirty [30] days after the institution decides to begin an

investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;

- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive 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 be notified that any comments must be submitted within thirty (30) days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the Research Integrity Officer and/or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.

D. Deciding Official

The Deciding Official will receive the inquiry report and after consulting with the Research Integrity Officer and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the Deciding Official and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within thirty (30) days of the finding. If it is found that an investigation is not warranted, the Deciding Official and the Research Integrity Officer will ensure that detailed documentation of the inquiry is retained for at least seven (7) years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.

The Deciding Official will receive the investigation report and, after consulting with the Research Integrity Officer and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The Deciding Official shall ensure that the final investigation report, the findings of the Deciding Official and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with the University of Delaware 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 call the Research Integrity Officer at (302) 831-4007 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 confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant, Witnesses, and Committee Members

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.

Also the institution 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 institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.

C. Protecting the Respondent

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

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

advice and may bring the counsel or personal adviser to interviews or meetings on the case.

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.

V. **Conducting the Assessment and Inquiry**

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the Research Integrity Officer need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The Research Integrity Officer shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the Research Integrity Officer determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the Research Integrity Officer must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins whichever is earlier, the Research Integrity Officer must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the

research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that 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. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

D. 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 as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

E. Charge to the Committee and First Meeting

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

- Sets forth the time for completion of the inquiry;
- Describe the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

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 will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the Research Integrity Officer, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the Deciding Official on whether an investigation is warranted, must be completed within sixty (60) calendar days of initiation of the inquiry, unless the Research Integrity Officer determines that circumstances clearly warrant a longer period. If the Research Integrity Officer approves an extension, the inquiry record must include documentation of the reasons for exceeding the sixty (60) day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the source of funding support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted 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 counsel will review the report for legal sufficiency.

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

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is

identifiable, with portions of the draft inquiry report that address the complainant'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 ten (10) calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the Inquiry Committee. Any comments that the complainant or respondent submit on the draft report will become part of the final inquiry report and record. Based on the comments, the Inquiry Committee may revise the report as appropriate.

- C. Institutional 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 research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within sixty (60) days of the first meeting of the Inquiry Committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the complainant in writing of the Deciding Official's decision of whether an investigation is warranted 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 the Deciding Official decides that an investigation is not warranted, the Research Integrity Officer shall secure and maintain for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by the cognizant agency of the reasons why an investigation was not conducted. These documents must be provided to the cognizant agency or other authorized personnel upon request.

- 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 forty-five (45) calendar days following its first meeting, 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 the report. The respondent also will be notified of the extension.

VII. Conducting the Investigation

A. Initiation and Purpose of the Investigation

The investigation must begin within thirty (30) calendar days after the determination by the Deciding Official that an investigation is warranted. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important 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. Notifying the Cognizant Agency; Sequestration of the Research Records on or before the date on which the investigation begins, the Research Integrity Officer must:**
- 1) notify the cognizant agency of the decision to begin the investigation and provide the agency a copy of the inquiry report; and 2) notify the respondent in writing of the allegations to be investigated. The Research Integrity Officer must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

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.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within ten (10) days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three

individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the Inquiry Committee. 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 or expert based on bias or conflict of interest within five (5) calendar days, the Research Integrity Officer will, at his/her sole discretion, determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the 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 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, the 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.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures 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 external funding is involved, the appropriate agency regulations.

E. Investigation Process

The investigation committee will be appointed and the process initiated within thirty (30) days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews 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.

VIII. The Investigation Report

A. Elements of the Investigation Report

The final report submitted to the cognizant 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.

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 thirty (30) calendar days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. 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 should be modified, as appropriate, based on the complainant's comments.

3. Institutional Counsel

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

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and 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 sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

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

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the complainant 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 to the Cognizant Agency

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the Deciding Official, through the Research Integrity Officer. The Deciding Official will transmit the final report to the cognizant agency.

E. Time Limit for Completing the Investigation

An investigation should ordinarily be completed within one-hundred-twenty days (120) days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the

report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the cognizant agency.

IX. Requirements for Reporting

- A. An institution's decision to initiate an investigation must be reported in writing to the cognizant agency, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the definition of research misconduct, and the grant applications or grant number(s) involved. The cognizant agency must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to the cognizant agency.
- B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the cognizant agency, the Research Integrity Officer will submit a report of the planned termination to the cognizant agency, including a description of the reasons for the proposed termination.
- C. If the institution determines that it will not be able to complete the investigation in one-hundred-twenty days (120) days, the Research Integrity Officer will submit to the cognizant 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 reports as requested by the cognizant agency.
- D. When Federal funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact the cognizant 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 research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from the cognizant agency.
- E. The Research Integrity Officer will notify the cognizant agency at any stage of the inquiry or investigation if:
 - 1. there is an immediate health hazard involved;
 - 2. there is an immediate need to protect Federal funds or equipment;
 - 3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
 - 4. it is probable that the alleged incident is going to be reported publicly; 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 the cognizant agency within 24 hours of obtaining that information.

X. Institutional Administrative Actions

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

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

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 research misconduct has been reported, will not preclude or terminate the misconduct procedures.

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

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and the cognizant agency 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. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others

Regardless of whether the institution or the cognizant agency 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 Deciding Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. 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 Complainant.

D. Allegations Not Made in Good Faith

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

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.

XII. Records 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 seven (7) years after completion of the case to permit later assessment of the case. The cognizant agency or other authorized personnel will be given access to the records upon request.

Effective 09/2007