

# RESEARCH POLICY 6 (RP-6) (FORMER RP/TAP-42) RESEARCH INTEGRITY

#### 1. Introduction

This Research Policy defines Research Misconduct and describes the procedures for handling allegations of Research Misconduct at Duquesne University. The responsibility to pursue a report of alleged Research Misconduct belongs to the University and the Review Process described in this Research Policy will be carried out fully to resolve questions regarding the integrity of the research.

# 2. Policy Statement

Researchers have the responsibility both to report actual or suspected occurrences of Research Misconduct and to take steps to correct the scientific record where appropriate. In many cases, however, a researcher may not be able to determine whether the concern regarding a research project constitutes Research Misconduct or simply error. The University strongly encourages anyone with concerns about impropriety in a research project to report those concerns to the Office of Research and Innovation (ORI) as further described in this Research Policy. Even in the absence of a specific complaint, ORI should be alerted to questionable research practices that might raise legitimate suspicion of research misconduct. ORI can provide guidance in ambiguous situations. If the inquiry indicates possible criminal violation, the Office of Research Integrity must be notified within 24 hours of obtaining that information.

Except to the extent described herein and as otherwise permissible by law, only those individuals with a need to know in order to perform their job duties and/or effectuate the Review Process will have access to research misconduct cases, as these are confidential proceedings.

The sponsoring entity for a research grant or award in which misconduct is suspected shall be notified by the Vice Provost for Research in writing as soon as the decision has been made to undertake an investigation, and no later than on the date the investigation begins. Sponsoring entity guidelines for such situations shall be followed and the sponsoring entity will be notified of the final finding and sanctions, if any. The University's process runs concurrently with any process undertaken by the agency, if applicable. In the case of Public Health Service (PHS) grants, notification is made to the Director of the Office of Research Integrity. The University also will notify the sponsoring entity at any stage of an inquiry or investigation if it is ascertained that any of the following conditions exist:

- 1. There is an immediate health and/or environmental 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 making the allegations or of the individual 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.

In the case of PHS grants, the University will follow the specific requirements under the PHS Policies on Research Misconduct – 42 CFR Part 93, which are attached as Appendix A.

After the University has notified the sponsoring entity that an investigation is warranted, or that any of the conditions listed above exist, the sponsoring entity may take interim action for reasons that include protecting the rights of involved parties and protecting the welfare of human or animal subjects of research. Interim action does not constitute a finding of Research Misconduct, but is a precautionary measure when necessitated by serious circumstances. Such interim action may include minor restrictions, requests for assurances, deferral of a continuation grant application, or suspension of the grant/suspension of the activities of the subject of the allegations (the "Respondent").

## 3. Policy Scope

The Research Policy applies to everyone involved in funded or unfunded research activities at Duquesne University, including students.

#### 4. Definition of Research Misconduct

The following is the definition of Research Misconduct for the purposes of this Research Policy. This definition may not necessarily conform to customary usage.

The key to defining Research Misconduct is intent. Research Misconduct is an act of deception. It is different from error or from honest differences in interpretation of data. The term Research Misconduct includes the following:

- 1. Falsification of data ranging from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results.
- 2. Plagiarism: representation of another's work as one's own.
- 3. Misappropriation of others' ideas.
- 4. The unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.
- 5. Formally presenting findings based on any other research practices that seriously deviate from those that are reasonable and commonly accepted within the scientific community for proposing, conducting, or reporting research.

#### **5. The Review Process**

# 5.1 Reporting Allegations of Research Misconduct

Allegations of Research Misconduct should be reported to the Vice Provost for Research or the Senior Director of Sponsored Research and Compliance for discussion and possible referral to the University Committee on Research Misconduct (the "Committee"). Allegations may be submitted orally or in writing, but Complainants are encouraged to submit allegations of Research Misconduct in writing so as to assure a clear understanding of the issues.

The Vice Provost for Research and/or the Senior Director of Sponsored Research and Compliance will meet with the individual reporting the alleged Research Misconduct (the "Complainant"), and the purpose of this initial meeting is to provide advice to the Complainant and determine whether the report falls within the scope of this Research Policy.

Some reports will fall outside the scope of this Research Policy, and in such cases, the report will be referred to the appropriate other institutional processes. If, however, the report does fall within scope of this Research Policy, the Vice Provost for Research and/or the Senior Director of Sponsored Research and Compliance will discuss with the Complainant the formal process for addressing the report, including the Complainant's option to make a formal allegation of Research Misconduct (the "Review Process"). If the Complainant chooses to make a formal allegation, the matter will be brought before the Committee as soon as possible. If the Complainant chooses not to make a formal allegation but the Vice Provost for Research and/or the Senior Director of Sponsored Research believe that Committee referral is necessary, the matter will be referred to the Committee for appropriate action.

#### **5.2** The Committee

The Committee will consist of 5 tenured faculty members appointed by the Provost. One Committee member will serve as the Committee Chair.

Committee representation will reflect the broad range of academic disciplines at the University. The Committee will interpret the University's Research Policy on Research Misconduct and will initiate and carry out inquiries and investigations. The Committee must ensure that it has the academic expertise necessary to judge the allegations being made. Therefore, subject to the approval of the Provost, it may call in on- or off-campus consultants as necessary to assist in reviewing a matter. Additionally, if a member of the Committee has a real or apparent conflict of interest with a given matter, and/or if a member of the Committee has a close professional or personal affiliation with the Complainant or the Respondent, that member will not participate in the Review Process. In such a case, the Committee will recommend to the Provost an ad hoc member to substitute. Review Process proceedings require a majority of the Committee in attendance.

The composition of the Committee may be challenged due to perceived bias or other concerns by the Respondent or by the Complainant. The Chair of the Committee will decide the validity of a challenge. In the event the Chair is challenged, the Provost will decide the validity of the challenge.

The Committee's review consists of two phases which are described below: an inquiry and, if it is determined from the inquiry that it is warranted, an investigation.

# **5.3 Review Process Participation**

All participants involved in the Review Process are expected to cooperate fully and to conduct themselves in an ethical manner. Participants have an obligation to strive for fairness and objectivity, with ample respect for the care needed in reviewing allegations of Research Misconduct and the harm that can result from unfounded allegations. Participants should focus on the substance of the report and not allow personal conflicts between colleagues to obscure the facts.

Even if the Respondent leaves the University before the matter is resolved, the University will complete the Review Process in accordance with this Research Policy. If there is a finding of Research Misconduct, the University will notify the institution with which the subject of the investigation is currently affiliated if applicable, and will cooperate with other institutions' processes to resolve any questions.

# **5.4 Inquiry**

#### A. Purpose

During the inquiry, factual information is gathered and expeditiously reviewed to determine, by majority, if an investigation of the allegation is warranted. An inquiry is not a formal hearing; it is designed to identify sufficiently credible and specific allegations which fall within the definition of Research Misconduct. Such allegations will be investigated.

# **B. Inquiry Process**

At the outset of an inquiry, the Committee convenes and notifies the Respondent of the basis of the inquiry and the process that will follow. Notification will be made in writing and copies will be securely maintained and held confidential in the Office of Research and Innovation. Whether a matter can be reviewed effectively without the involvement of the Complainant in the Committee proceedings depends upon the nature of the allegation and the evidence available. Matters that depend specifically on the observations or statements of the Complainant cannot proceed without the involvement of the Complainant in the Committee proceedings.

The Respondent is obligated to cooperate in providing the material necessary to conduct the inquiry and will be so informed by the Committee when the inquiry is initiated. Uncooperative behavior may result in immediate implementation of a formal investigation and any sanctions

as appropriate if a finding of research misconduct is made. The Respondent will be given an opportunity to respond to the allegations during the inquiry.

At the completion of the inquiry, the Committee will complete a report of the inquiry findings. Prior to finalizing such findings, the Respondent will have an opportunity to respond to a draft report of the inquiry findings. If the Respondent comments on that report, the comments will be made part of the final inquiry record.

Inquiries will be resolved expeditiously. The date the Committee convenes to consider an allegation or evidence of Research Misconduct marks the beginning of the time period allowed for conducting the inquiry. The inquiry phase must be completed and the final written report of the inquiry findings submitted to the Provost within 60 business days of initiation of the inquiry, unless circumstances clearly warrant a longer period, or within a shorter time period if so specified by a sponsoring entity. If the Committee anticipates that the established deadline cannot be met, it shall submit to the Provost a report citing the reason(s) for the delay and describing progress to date; it shall also inform the Respondent and other involved individuals. Further, the record of inquiry must include documentation of the reason for exceeding the 60-day period.

# C. Findings of the Inquiry

The completion of an inquiry is marked by a determination of whether or not an investigation is warranted, and by submission of the written report of the inquiry findings to the Provost. The report shall state what evidence was reviewed, summarize relevant interviews, and describe the process and conclusion of the inquiry. It shall be sufficiently detailed to permit a later assessment of the reasons supporting the inquiry finding. The report and all other inquiry records will be retained in a confidential and secure file in ORI for at least 7 years after the final resolution date of the matter. The Respondent and the Complainant will be informed by the Committee with regard to whether the allegations will be subject to an investigation. The Respondent will be given a copy of the final report of the inquiry findings.

In the case of allegations found to warrant an investigation, the Provost will notify the director(s) and/or appropriate individual(s) within the sponsoring entity that an investigation will be conducted (see next section). In addition, the Committee will notify the Respondent's department chair and dean (if applicable) of the impending investigation.

If an allegation is found to be unsupported but that it has been submitted in good faith, no further formal action, other than informing all parties involved in the inquiry, shall be taken. In such cases the University will undertake diligent efforts to protect the Complainant against retaliation. Individuals engaging in acts of retaliation will be subject to disciplinary action and/or grievance proceedings. Unsupported allegations not brought in good faith shall lead to disciplinary action against the Complainant through the appropriate University Office.

# 5.5 Investigation

# A. Purpose

An investigation is the formal examination and evaluation of all pertinent facts to determine whether Research Misconduct has occurred. The investigation findings and recommendations are advisory. They will be submitted to and reviewed by the Provost, who will make the final finding on the matter.

#### **B. Process**

Following a finding that an investigation is warranted, the Committee will initiate the investigation within 30 business days of the date on which its report of inquiry findings was submitted to the Provost. The Committee's procedures in conducting the investigation shall be in compliance with any sponsoring entity guidelines that must be followed if the research is supported by external funding. See Appendix A for PHS policies on Research Misconduct. The investigation may consist of a combination of activities including, but not limited to:

- 1. Review and copying of relevant research data, proposals, correspondence, memoranda of telephone calls or memoranda to file, and other pertinent documents at the University, at the sponsoring entity, or elsewhere.
- 2. Review of published materials and manuscripts submitted or in preparation.
- 3. Inspection of offices, laboratory or clinical facilities, and/or materials.
- 4. Interviewing of individuals with an involvement in or knowledge about the report, including both the Complainant and the Respondent, as well as witnesses. Complete summaries of these interviews shall be prepared, provided to the individual interviewed, and included as part of the documentary record of the investigation. The interviewed individual may provide a response, which will also be included as part of the documentary record of the investigation.

In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations, and the Respondent will be informed accordingly.

The Committee shall notify the Provost of any major developments that could warrant interim action or that must be reported to the sponsoring entity (see Policy Statement). In the latter case, as further discussed in the Policy Statement, such developments include disclosure of facts that may affect current or potential funding for the individual(s) under investigation or that the sponsoring entity needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. Additionally, significant developments during the investigation will be reported in writing by the Provost to the sponsoring entity as necessary, in accordance with sponsoring entity guidelines.

After conducting the investigation in accordance with the process outlined above, the Committee will develop a preliminary report. The preliminary report shall include at least the following: a description of the policies and procedures under which the investigation was conducted; a description of how and from whom or where information relevant to the investigation was obtained; a specific statement of the Committee's preliminary investigative findings relative to possible Research Misconduct, or the lack thereof, and the basis of those findings; and a statement of the Committee's recommendations for resolution of the matter, including recommended sanctions, if any, and the rationale in support thereof. All written materials and other documents forming part of the record, including interview summaries, shall be attached to the preliminary report. Tangible scientific property, e.g. slides, specimens, etc., shall be incorporated into the report by reference and retained in the custody or control of the Committee Chair until such time as the process is over.

A copy of the preliminary report, including all attachments, will be provided to the Respondent for the purpose of affording him or her the opportunity to respond. The Respondent will be given at least 10 business days to respond to the preliminary report. The Respondent will be informed that he or she has the right to respond in writing and to request the opportunity to meet with the Committee. Should the Respondent elect to meet with the Committee, he or she will be permitted to make an oral presentation to the Committee and to present documentary, testimonial, and rebuttal evidence. Following the conclusion of any such meeting held with the Respondent and after receipt of the Respondent's written response to the preliminary report, if applicable, the Committee will have the responsibility to carefully review and consider the entire record in the matter, to conduct further investigation if necessary, and to prepare a final investigative report setting forth the detailed findings of the Committee (see Findings of the Investigation below) and any recommended sanctions. The final report shall parallel the preliminary report in format and shall include the same categories of information. It shall also include the actual text and/or an accurate summary of the response of the Respondent.

The Committee then will submit the final investigative report to the Provost. The Respondent also will receive the final report of the investigation. When there is more than one Respondent, each will receive all those parts of the investigative report that are pertinent to his or her role. The Complainant shall be provided with those portions of the final report that address his or her role and opinions in the investigation.

Investigations shall be conducted as expeditiously as practical. An investigation ordinarily shall be completed within 120 business days of its initiation (including submission of the final report to the sponsoring entity). However, the nature of some matters may render the deadline difficult to meet. If the Committee determines that the full process cannot be completed in 120 days, it must notify the Provost of the reason for the delay and ask for an appropriate extension of time. In the case of PHS grants, the following procedure will then apply: the Provost will submit to the ORI a written request for an extension, including an interim report from the Committee on its progress to date and an estimate for the date of completion of the report and other necessary steps. Any request for extension must balance the need for a thorough and rigorous examination of the facts and the interests of the Respondent and the sponsoring entity in a timely resolution of the matter.

If the request is granted, the appropriate University Office will file periodic progress reports as requested by ORI. Non-PHS sponsoring entities may have other guidelines or regulations to be followed. If the deadline cannot be met in an investigation of research that involves no external funding, the Committee shall submit an interim report to the Provost.

The investigation is complete when the Provost has reviewed the report, made a final finding on the matter, and submitted to the sponsoring entity the final investigative report along with a description of any sanctions to be taken by the University. All parties involved will be notified of the outcome by the Provost.

### C. Findings of the Investigation

The Provost will review the Committee report and make a final finding on the matter. Findings of an investigation will be one of the following:

- 1. Research misconduct was committed.
- 2. No misconduct was committed, but serious scientific errors were discovered in the course of the investigation.
- 3. No misconduct or serious scientific error was committed.

The findings and other records of the investigation will be securely and confidentially maintained, in accordance with pertinent sponsoring entity guidelines, and federal and state laws, in a file in the Office of Research and Innovation.

The University will carry its investigation through to completion and will pursue diligently all significant issues. If the University anticipates terminating an inquiry or investigation for any reason without completing all requirements outlined above, a report of such planned termination, including a description of the reasons for such termination, will be sent to all parties and sponsoring entities involved.

The section below titled Resolution details the follow-up action that must be taken after the finding is made.

# **D.** Resolution

# 1. Finding of No Research Misconduct

All persons and entities informed of the investigation must be notified promptly of the finding of no misconduct. Notification will be made by the Provost, who will undertake diligent efforts, as appropriate, to restore the reputation of the Respondent when there is a finding of no misconduct.

# 2. Finding of No Research Misconduct, But Finding of Serious Scientific Error

All persons and entities informed of the investigation must be notified promptly of the finding of no misconduct but serious scientific error. Notification will be made by the Provost. Additionally, the University will need to correct the scientific record. The Provost will refer these recommendations to the appropriate administrative official (department chair, dean, or higher administrator) for follow-up action.

# 3. Finding of Research Misconduct

All persons and entities informed of the investigation must be notified promptly of the finding of research misconduct. Notification will be made by the Provost. In its final report, the Committee will recommend necessary actions to correct the scientific record and to notify affected individuals or entities as discussed above. The Provost will refer these recommendations to the appropriate administrative official (department chair, dean, or higher administrator) for follow-up action.

As more fully discussed above, sanctions will also be assigned. Sanctions can range from a reprimand or removal from the research project to termination of employment. Sanctions are subject to provisions of appeal as specified in Section 5.6.

# 5.6 Appeal/Final Review

The Respondent may file a written appeal of the determination of the Provost with the President of the University in accordance with University grievance procedures. Sanctions are held in abeyance pending the outcome of the appeal. The sponsoring entity will be apprised of the appeal. The decision of the President shall be final. Any appeal should be filed within 30 business days after the Provost determination. The appeal is restricted to the body of evidence already presented, and the grounds for appeal are limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision making. In the case of PHS grants, any appeal process must be completed within 120 days unless the University has requested and received an extension from the Office of Research Integrity. This 120-day deadline does not apply to institutional termination hearings that are conducted separately from the appeal process.

## 6. Exceptions

Exceptions to this Research policy and procedures require approval from the Vice Provost for Research and normally will be made with the agreement of those involved in the Research Misconduct Committee and any others involved in the resolution of the misconduct. Any exceptions must be in full accordance with the regulations of the sponsoring entity.

# 7. Related Documents

This Research Policy works in conjunction with the following Research and University Policies, which are fully applicable. To the extent there is any conflict between this Research Policy and any of the Research or University Policies listed below, the University retains the sole discretion to determine which takes precedent.

Research Policy/TAP	Title	Web Address
RP-1	Procedure for Submitting External Sponsored Grants and Awards	https://www.duq.edu/research/research- conduct
RP-2	The Use of Human Subjects in Research	https://www.duq.edu/research/research- conduct
RP-3	Effort Reporting on Sponsored Grants and Awards	https://www.duq.edu/research/research- conduct
RP-4	Faculty Research Proposals to Governmental, Corporate, Foundation and Private Sources	https://www.duq.edu/research/research- conduct
RP-5	Intellectual Property	https://www.duq.edu/research/research- conduct
RP-7	Conflicts of Interest in Sponsored Grants and Awards	https://www.duq.edu/research/research- conduct
RP-8	Research Agreements and Private Business Use	https://www.duq.edu/research/research- conduct
TAP-33	Conflict of Interest	https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/33-conflict-of-interest
TAP-46	Commercial Entities—Faculty, Staff and Student Participation	https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/46-commercial-entities% E2% 80% 94 faculty-staff-and-student-participation

# 7. Contacts

Office	<b>Telephone Number</b>	Email Address and/or URL
Office of Research and Innovation	412-396-6326	duq.edu/research ORI@duq.edu

Web Address for this Research Policy: https://www.duq.edu/research/research-conduct

# 8. Effective Date and Revision History

This Research Policy is subject to periodic review and update by the Office of the Provost and the Vice Provost for Research.

9/3022 (Previous revision was not dated)

# Appendix A

# **Policies - Regulations**

# Requirements for Institutional Policies and Procedures on Research Misconduct Under the PHS Policies on Research Misconduct - 42 CFR Part 93

**Effective Date:** The new final rule on research misconduct is published at 70 Federal Register (FR) 28370 (May 17, 2005) (subsequently codified at 42 CFR Part 93) and became effective on June 16, 2005.

The final rule is also posted on the ORI home page (see top links) at <a href="http://ori.dhhs.gov/">http://ori.dhhs.gov/</a>)

#### Research Misconduct Proceedings-Criteria, Reports, and Time Limitations

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, we shall assess the allegation to determine if: (1) it meets the definition of research misconduct in 42 CFR Section 93.103; (2) it involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b); and, (3) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If it is determined that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted, we shall complete the inquiry, including preparation of the inquiry report and giving the Respondent a reasonable opportunity to comment on it, within 60 calendar days of its initiation, unless the circumstances warrant a longer period. If the inquiry takes longer than 60 days to complete, we shall include documentation of the reasons for the delay in the inquiry record. The inquiry report shall contain the following information: (1) The name and position of the Respondent(s); (2) A description of the allegations of research misconduct; (3) The PHS support involved, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support; (4) The basis for recommending that the alleged actions warrant an investigation; and (5) Any comments on the report by the Respondent or the Complainant.

The Provost/Vice President for Academic Affairs will make a written determination of whether an investigation is warranted. If the inquiry results in a determination that an investigation is warranted, we shall begin the investigation within 30 calendar days of that determination and, on or before the date on which the investigation begins, send the inquiry report and the written determination to the ORI. We shall use our best efforts to complete the investigation within 120 calendar days of the date on which it began, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI. If it becomes apparent that we cannot complete the investigation within that period, we shall promptly request an extension in writing from ORI.

In conducting all investigations, we shall: (1) Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and

evidence relevant to reaching a decision on the merits of the allegations; (2) Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation; (3) Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion; and (4) Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310.

We shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312. The final investigation report shall:

- (1) Describe the nature of the allegations of research misconduct;
- (2) Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;
- (3) Describe the specific allegations of research misconduct considered in the investigation;
- (4) Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI;
- (5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. The report should also describe any relevant records and evidence not taken into custody and explain why.
- (6) Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, (i) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard, (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the Respondent and any evidence that rebuts the Respondent's explanations, (iii) identify the specific PHS support; (iv) identify any publications that need correction or retraction; (v) identify the person(s) responsible for the misconduct, and (vi) list any current support or known applications or proposals for support that the Respondent(s) has pending with non-PHS Federal agencies; and
- (7) Include and consider any comments made by the Respondent and Complainant on the draft investigation report.

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

#### **Ensuring a Fair Research Misconduct Proceeding**

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

#### **Notice to Respondent**

During the research misconduct proceeding, we shall provide the following notifications to all identified Respondents:

- **Initiation of Inquiry.** Prior to or at the beginning of the inquiry, we shall provide the Respondent(s) written notification of the inquiry and contemporaneously sequester all research records and other evidence needed to conduct the research misconduct proceeding. If the inquiry subsequently identifies additional Respondents, they shall be promptly notified in writing.
- **Comment on Inquiry Report.** We shall provide the Respondent(s) an opportunity to comment on the inquiry report in a timely fashion so that any comments can be attached to the report.
- **Results of the Inquiry.** We shall notify the Respondent(s) of the results of the inquiry and attach to the notification copies of the inquiry report and these institutional policies and procedures for the handling of research misconduct allegations.
- **Initiation of Investigation.** Within a reasonable time after our determination that an investigation is warranted, but not later than 30 calendar days after that determination, we shall notify the Respondent(s) in writing of the allegations to be investigated. We shall give Respondent(s) written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.
- **Scheduling of Interview.** We will notify the Respondent sufficiently in advance of the scheduling of his/her interview in the investigation so that the Respondent may prepare for the interview and arrange for the attendance of legal counsel, if the Respondent wishes.
- Comment on Draft Investigation Report. We shall give the Respondent(s) a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the Respondent(s) that any comments must be submitted within 30 days of the date on which he/she received the draft report. We shall ensure that these comments are included and considered in the final investigation report.

# Notifying ORI of the Decision to Open an Investigation and of Institutional Findings and Actions Following the Investigation.

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of our finding that an investigation is warranted), we shall provide ORI with the written finding by the Provost/Vice President for Academic Affairs and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a). Upon a request from ORI we shall promptly send them: (1) a copy of our institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider.

We shall promptly provide to ORI after the investigation: (1) A copy of the investigation report, all attachments, and any appeals; (2) A statement of whether the institution found research misconduct and, if so, who committed it; (3) A statement of whether the institution accepts the findings in the investigation report; and (4) A description of any pending or completed administrative actions against the Respondent.

#### Maintenance and Custody of Research Records and Evidence

We shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

- (1) Either before or when we notify the Respondent of the allegation, we shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- (2) Where appropriate, give the Respondent copies of, or reasonable, supervised access to the research records.
- (3) Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (1) above.
- (4) We shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless we have transferred custody of the records and evidence to HHS, or ORI has advised us that we no longer need to retain the records.

#### **Interim Protective Actions**

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

#### Notifying ORI of Special Circumstances that may Require Protective Actions

At any time during a research misconduct proceeding, we shall notify ORI immediately if we have reason to believe that any of the following conditions exist:

- (1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (2) HHS resources or interests are threatened.
- (3) Research activities should be suspended.
- (4) There is a reasonable indication of violations of civil or criminal law.
- (5) Federal action is required to protect the interests of those involved in the research

misconduct proceeding.

- (6) We believe the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (7) We believe the research community or public should be informed.

# Institutional Actions in Response to Final Findings of Research Misconduct

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

#### **Restoring Reputations**

**Respondents.** We shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that we do so.

Complainants, Witnesses, and Committee Members. We shall undertake all reasonable and practical efforts to protect and restore the position and reputation of any Complainant, witness, or committee member and to counter potential or actual retaliation against those Complainants, witnesses and committee members.

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

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