

# **The Administrative Policies**

## **TAP NO. 42: RESEARCH INTEGRITY**

This policy defines research misconduct and describes the procedures for handling allegations of research misconduct at Duquesne University at Pittsburgh, PA. The policy applies to everyone involved in funded or unfunded research activities at Duquesne University, including students.

The University strongly encourages anyone with concerns about impropriety in a research project to communicate those concerns through appropriate channels. If they cannot be communicated directly to the researchers involved, or if such action has an unsatisfactory result, the procedures outlined in this document provide a recourse.

The policy defines research misconduct as an act of deception, distinct from error. Researchers have the responsibility both to report apparent occurrences of misconduct and to take steps to correct the scientific record when they discover error. In many cases, however, a person may not be able to determine whether the problem he or she perceives with a research project constitutes misconduct or error. The people listed in this document to whom formal allegations should be brought can provide guidance in ambiguous situations.

The responsibility to pursue an allegation of research misconduct belongs to the University and must be carried out fully to resolve questions regarding the integrity of the research. Even in the absence of a specific complaint, the University should be alert to questionable research practices that might raise legitimate suspicion of research misconduct.

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

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

In the event of a case of alleged misconduct, all persons involved in the proceedings are expected to cooperate fully and to conduct themselves in an ethical manner. They have an obligation to strive for fairness and objectivity, with ample respect for the care needed in reviewing allegations of misconduct and the harm that can result from unfounded allegations. They should focus on the substance of the issues and not allow personal conflicts between colleagues to obscure the facts.

### **DEFINITION OF RESEARCH MISCONDUCT**

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 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, the unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.
4. Formally presented 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.

## **PROCESS FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT**

The review process for cases of alleged misconduct consists of two phases: an inquiry and, if it is determined from the inquiry that it is warranted, an investigation. Procedures for both phases are described below. Also, described are procedures for reporting to the funding agency (where applicable) and taking interim administrative action when serious circumstances call for immediate precautions. There are also provisions for appealing a determination of research misconduct.

In case of an alleged misconduct, and in order to address such allegations expeditiously, the University will form a Committee to be known as the University Committee on Research Misconduct. The Committee will consist of 5 tenured faculty members appointed by the Provost/Vice President for Academic Affairs. Committee representation should reflect the broad range of academic disciplines at the University. The Committee will interpret the University's policy on research misconduct and will initiate and carry out inquiries and investigations.

Allegations may be reported to the chair of the Committee, the Dean, the Associate Academic Vice President for Research or the Director of Sponsored Research for discussion and possible referral to the Committee. Any of these persons may counsel confidentially any individual who comes forward with an allegation of misconduct. Some concerns brought to their attention may not fall within the scope of the policies and procedures developed to address misconduct, and in such cases they will refer the matter to whatever institutional processes may be appropriate to the particular case. If they determine that the concern does fall under the jurisdiction of the University Committee on Research Misconduct, they will discuss the inquiry and investigation procedures with the individual who has questions about the integrity of a research project (the complainant). If the individual chooses to make a formal allegation, the matter will be brought before the Committee as soon as possible. If the individual chooses not to make a formal allegation but the administrator or Committee chair believes there is sufficient basis for conducting an inquiry, the matter will be referred to the Committee for appropriate action.

Even if the subject of the allegations (the respondent) leaves the University before the case is resolved, the University will continue the examination of the allegations in accordance with this policy. If there is a finding of misconduct, the University will notify the institution with which the subject of the investigation is currently affiliated. Furthermore, the University will cooperate with other institutions' processes to resolve such questions.

### **A. INQUIRY**

#### **1. PURPOSE**

An inquiry, the first step of the review process, may be initiated by an allegation of misconduct or by information obtained from other sources, such as review of reports. Whenever an allegation or other information involving the possibility of misconduct is brought before it, the University Committee on Research Misconduct will initiate an inquiry. In the inquiry, factual information is gathered and expeditiously

reviewed to determine if an investigation of the charge is warranted. An inquiry is not a formal hearing; it is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

## **2. STRUCTURE**

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 case. If a member of the Committee has a real or apparent conflict of interest with a given case, that member will not participate in the review process for the case. In such a case, the Committee will recommend to the Provost/ Vice President for Academic Affairs an ad hoc member to substitute. Inquiry proceedings require a majority of the Committee in attendance.

## **3. PROCESS**

To initiate 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. To the greatest extent possible, the inquiry proceedings will be kept confidential in order to protect the rights of all parties involved. Whether a case 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. Cases that depend specifically on the observations or statements of the complainant cannot proceed without the involvement of that individual in the Committee proceedings; other cases that can rely on documentary evidence may permit the complainant to remain anonymous to the Committee.

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 appropriate institutional sanctions. The respondent will be given an opportunity to comment on the allegations during the inquiry and to respond to a draft copy of the inquiry findings. If he or she comments on that report, the comments will be made part of the final inquiry record. Inquiries should be resolved expeditiously. The date the Committee convenes to consider an allegation or evidence of 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 findings submitted to the Provost/Vice President for Academic Affairs within 60 days of initiation of the inquiry, unless circumstances clearly warrant a longer period, or within a shorter time period if so specified by a funding agency. If the Committee anticipates that the established deadline cannot be met, it shall submit to the Provost/Vice President for Academic Affairs 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.

## **4. 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/Vice President for Academic Affairs. 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 the Office of Research for at least 3 years after the completion of the inquiry. The respondent and the complainant will be informed by the Committee whether or not the allegations will be subject to an investigation. The respondent will be given a copy of the final report of the inquiry.

In the case of allegations found to warrant an investigation, the Provost/Vice President for Academic Affairs will notify the director(s) of any funding agencies sponsoring the research in question 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 has been submitted in good faith, no further formal action, other than informing all parties involved in the inquiry, shall be taken. The records and findings of the inquiry, including the identity of the respondent, will be held confidential to the greatest extent possible to protect the parties involved. 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.

## **B. PROCEDURES FOR REPORTING TO THE FUNDING COMPONENT**

The agency sponsoring a research project in which misconduct is suspected shall be notified by the Provost/ Vice President for Academic Affairs in writing as soon as the decision has been made to undertake an investigation, and no later than on the date the investigation begins. Agency guidelines for such situations shall be followed. In the case of Public Health Services (PHS) grants, notification is made to the Director of the Office of Research Integrity (ORI). The University also will notify the funding agency 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. If the inquiry indicates possible criminal violation, the Office of Research Integrity must be notified within 24 hours of obtaining that information.

## **C. INTERIM ADMINISTRATIVE ACTION**

After the University has notified the funding agency that an investigation is warranted, or that any of the conditions listed in the preceding section exist, the agency may take interim action to protect the rights of involved parties, to protect the welfare of human or animal subjects of research, etc. Such action can range from minor restrictions, requests for assurances, or deferral of a continuation grant application all the way to suspension of the grant.

Interim administrative action also may be taken by the University in the event that any of the conditions listed in the preceding section exist. Interim action does not constitute a finding, but is a precautionary measure necessitated by serious circumstances. The Provost/Vice President for Academic Affairs may take such action when justified by the need to protect federal funds; the health and safety of research subjects and patients; research data, records, materials, or other information that may be the subject of an inquiry or investigation; or the interests of students, colleagues, or the general public.

Such action can range from minor restrictions to suspension of the activities of the respondent. Interim administrative action should be taken in full awareness of how it might affect the individuals and the ongoing research within the University.

## **D. INVESTIGATION**

### **1. PURPOSE**

The University Committee on Research Misconduct will initiate an investigation only after it has made an inquiry finding that an investigation is warranted. An investigation is the formal examination and evaluation of all pertinent facts to determine whether misconduct has occurred. Among other things, the investigation shall look carefully at the substance of the inquiry findings and examine all relevant evidence. The investigation findings and recommendations are advisory. They will be submitted to and reviewed by the Provost/Vice President for Academic Affairs, who will make the final determination on the case. To the greatest extent possible, the investigation proceedings will be kept confidential. However, it should be noted that complete confidentiality cannot be assured during an investigation, which is a much more formal, wideranging proceeding than an inquiry.

### **2. STRUCTURE**

Any Committee member who has a close professional or personal affiliation with the complainant or the respondent in a given case shall not participate in the investigation of that case. The Committee shall request that the Provost/Vice President for Academic Affairs appoint an ad hoc member to substitute for any nonparticipating member. Investigation proceedings require a majority of the Committee in attendance.

Committee members shall be unbiased, have appropriate academic backgrounds for judging the issues being raised, and have no real or apparent conflicts of interest with the case being investigated. The composition of the Committee may be challenged for cause by the respondent or by the complainant (if any); the Chair of the Committee will decide the validity of a challenge for cause. In the event the Chair is challenged for cause, the Provost/ Vice President for Academic Affairs will decide the validity of the challenge. As in an inquiry, the Committee may call in on- or off-campus consultants as necessary to assist it in the investigation.

### **3. PROCESS**

Upon completing an inquiry and finding that an investigation is warranted, the University Committee on Research Misconduct will initiate the investigation within 30 days of the date on which its report was submitted to the Provost/Vice President for Academic Affairs. To the extent feasible, the Committee's procedures in conducting the investigation shall be in compliance with any agency guidelines that must be followed if the research is supported by external funding. The investigation may consist of a combination of activities including, but not limited to:

- a. 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 granting agency, or elsewhere.
- b. Review of published materials and manuscripts submitted or in preparation.
- c. Inspection of offices, laboratory or clinical facilities, and/or materials.
- d. Interviewing of parties with an involvement in or knowledge about the case, including both the complainant and the respondent. Complete summaries of these interviews shall be prepared, provided to the interviewed party for comment or revision, and 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. The respondent shall be informed when significant new directions of investigation are undertaken. The Committee shall notify the Provost/Vice President for Academic Affairs of any major developments that could warrant interim action or that must be reported to the funding agency. In the latter case, such developments include disclosure of facts that may affect current or potential funding for the individual(s) under investigation or that the funding agency needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. Significant developments during the investigation will be reported in writing by the Provost/Vice President for Academic Affairs to the funding agency as necessary, in accordance with agency 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 misconduct in research, 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. 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 calendar 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 accompanied by an adviser of choice. 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. A transcript of the meeting will be made available to the respondent. Following the conclusion of any such meeting held with the respondent and after receipt of the respondent's written response to the preliminary report, 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 or an accurate summary of the response of the respondent.

The Committee then will submit the final investigative report to the Provost/Vice President for Academic Affairs. 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 report that are pertinent to his or her role.) If the identity of the complainant is known to the Committee, he or she shall be provided with those portions of the final report that address his or her role and opinions in the investigation. The investigation is complete when the Provost/Vice President for Academic Affairs has reviewed the report, made a determination on the case, and submitted to the funding agency the final report along with a description of any sanctions to be taken by the University. Investigations shall be conducted as expeditiously as possible. An investigation ordinarily shall be completed within 120 days of its initiation (including submission of the final report to the funding agency). However, the nature of some cases 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/ Vice President for Academic Affairs 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/Vice President for Academic Affairs will submit to the Office of Research Integrity 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 funding agency in a timely resolution of the matter.

If the request is granted, the University will file periodic progress reports as requested by ORI. Non-PHS funding agencies 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/ Vice President for Academic Affairs.

#### **4. FINDINGS OF THE INVESTIGATION**

Findings of an investigation may include the following:

- a. Research misconduct was committed.
- b. No misconduct was committed, but serious scientific errors were discovered in the course of the investigation.
- c. No misconduct or serious scientific error was committed.

The Provost/Vice President for Academic Affairs will review the Committee report and make a determination on the case. The section below titled Resolution details the follow-up action that must be taken after the determination is made.

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

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 funding agencies involved.

#### **E. APPEAL/FINAL REVIEW**

The respondent may file a written appeal of the determination of the Provost/Vice President for Academic Affairs with the President of the University in accordance with University grievance procedures. The decision of the President shall be final. Any appeal should be filed within 30 days after the Provost/Vice President for Academic Affairs determination. (A time extension, where there is appropriate justification, may be requested of the President.) The appeal should be restricted to the body of evidence already presented, and the grounds for appeal should be 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 ORI. This 120 day deadline does not apply to institutional termination hearings that are conducted separately from the appeal process.

#### **F. RESOLUTION**

##### **1. FINDING OF NO RESEARCH MISCONDUCT**

All persons and agencies/organizations informed of the investigation must be notified promptly of the finding of no misconduct. Notification will be made by the Provost/ Vice President for Academic Affairs. He will undertake diligent efforts, as appropriate, to restore the reputation of the respondent when there is a finding of no misconduct.

If the unsubstantiated allegations of misconduct are found to have been maliciously motivated, appropriate disciplinary action will be taken. If the allegations, however incorrect, are found to have been made in good faith, no disciplinary measures will be taken and efforts will be made to prevent retaliatory actions.

## **2. FINDING OF NO RESEARCH MISCONDUCT, BUT FINDING OF SERIOUS SCIENTIFIC ERROR**

All persons and agencies/organizations informed of the investigation must be notified promptly of the finding of no misconduct. Notification will be made by the Provost/ Vice President for Academic Affairs. The University will need to consider means to correct the scientific record. In the event that the Committee discovers serious scientific errors, it will include in its final report specific recommendations for action, such as notifying editors of journals in which the respondent's research was published, other institutions with which the respondent has been affiliated. collaborators, professional societies, state professional licensing boards (if applicable), etc. The Provost/Vice President for Academic Affairs will refer these recommendations to the appropriate administrative official (department chair, dean, or higher administrator) for follow-up action. The Committee's final report will be sent to affected funding agencies or other organizations as appropriate.

## **3. FINDING OF RESEARCH MISCONDUCT**

All persons and agencies/organizations informed of the investigation must be notified promptly of the finding of research misconduct. Notification will be made by the Provost/Vice President for Academic Affairs. In its final report, the Committee will recommend necessary actions to correct the scientific record and to notify affected individuals or organizations as specified in F.2 above. The Provost/Vice President for Academic Affairs will refer these recommendations to the appropriate administrative official (department chair, dean, or higher administrator) for follow-up action.

The Committee in its report also will recommend specific sanctions to be imposed on the respondent(s), including the reasons thereof. Sanctions can range from a reprimand or removal from the research project to termination of employment. The Provost/Vice President for Academic Affairs will then make determination of the appropriate sanction, subject to provisions of appeal as specified in Section E above. The Committee's final report will be sent, as appropriate, to affected funding agencies or other organizations, which may impose their own sanctions or take other action.

## **G. PERIODIC POLICY REVIEW**

The Office of the Secretary of the University and the Office of the Provost/Academic Vice President will be responsible for reviewing and revising this policy as required.

### **Appendix A**

#### **Policies - Regulations**

#### **Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct - 42 CFR Part 93 (Link)**

**Effective Date:** The new final rule on research misconduct is published at 70 Federal Register (FR) 28370 (May 17, 2005) (subsequently to be 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 <http://ori.dhhs.gov/> (<http://ori.dhhs.gov/>)

#### **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/Academic Vice President 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/Academic Vice President 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 case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

### **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.

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