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Purpose

The purpose of this policy is to define procedures for dealing with allegations of fraud and/or misconduct in research in an effort to further the University's goal to foster a research environment that promotes the responsible conduct of research, research training, and activities related to research or research training. Under this policy, the University strives to deal promptly with allegations or evidence of possible research fraud and/or misconduct.

The University strives to create a research climate that promotes faithful adherence to high ethical standards without inhibiting the productivity and creativity of persons involved in research. **Research misconduct** (including fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results; not including honest errors or differences in interpretations or judgments of data) is an offense that damages not only the reputation of those involved but also the University and the entire educational community.

Scope

This Policy sets forth the University's commitment to high ethical standards in research. It applies to Research misconduct involving a person who, at the time of the alleged Research Integrity, was employed by, was an agent of, or was affiliated by contract or agreement with the University.

When applicable, this Policy also carries out the University's responsibilities under the Public Health Service (PHS) Policies on Research misconduct (42 C.F.R. Part 93). It applies to Research misconduct involving:

- (1) PHS support biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information.
- (2) Applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training; or

(3) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

This Policy does not apply to authorship or collaboration disputes and applies only to allegations of Research misconduct that occurred within six years of the date the University or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

Policy

I. Definitions

Terms used in this Policy have the same meaning as given them in the Public Health Service Policies on Research Integrity, 42 CFR Part 93. In addition, this Policy uses the following defined terms:

Deciding Official (DO) means the University official who makes final determinations on allegations of Research misconduct and any University administrative actions. The Deciding Official will ordinarily be the President (or the President's designee) unless circumstances make another University official the appropriate Deciding Official. However, the Deciding Official will not be the same individual as the Research misconduct Officer (defined below) and should have no direct prior involvement in the University's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of Research Integrity, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

Research misconduct Officer (RIO) means the University official responsible for: (1) assessing allegations of Research misconduct to determine if they fall within the definition of Research Integrity, are covered by 42 C.F.R. Part 93 (when applicable), and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of Research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. The RIO will ordinarily be the appropriate Department Chair, Dean, or the President's designee. The University will take all reasonable and practical steps to ensure the RIO for a particular allegation of Research misconduct has applicable expertise and does not have an unresolved conflict of interest with those involved (personal, professional, financial, or otherwise).

II. Rights and Responsibilities

A. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, 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.

B. 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 by the RIO 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 (when applicable) and the University's
 policies and procedures on Research Integrity.
- 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 30 days after the University 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 30 days of the date on which the copy was received and that the comments will be considered by the University 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 Integrity. With the advice of the RIO and/or other University officials, the DO may terminate the University's review of an allegation that has been admitted (note: in matters where research was PHS-supported, the University's review of an admitted allegation may terminate only if the University's acceptance of the admission and any proposed settlement is approved by HHS's Office of Research misconduct(ORI)).

To the extent provided by university policy, the respondent may have an opportunity to request an appeal.

III. General Policies and Principles

A. Responsibility to Report Misconduct

All University members will report observed, suspected, or apparent Research misconduct to the appropriate RIO. If an individual is unsure whether a suspected incident falls within the definition of Research Integrity, he or she may meet with or contact the appropriate RIO to discuss the suspected Research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of Research Integrity, then the RIO receiving the information should refer the individual or allegation to the appropriate other office or official with responsibility for resolving the problem.

At any time, a university member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research misconduct Proceedings

University members will cooperate with the RIO and other University officials in the review of allegations and the conduct of inquiries and investigations. University members, including respondents, have an obligation to provide evidence relevant to Research misconduct allegations to the RIO or other appropriate University officials.

C. Research Ethics Training

For an investigator to design and conduct an ethical research project, they must understand how to conduct ethical research, how to protect the rights of their human subjects, and their responsibilities as researchers. Evidence of completion of research ethics training must be on file for <u>all</u> researchers associated with a project before it can be approved by the Northwest IRB. This includes any researchers involved with the project (whether through data collection, data analysis, or another part of the project), not just principal investigators.

Beginning Fall 2021, all researchers and IRB committee members (including student researchers) must complete the <u>Human Subjects Research (HSR) training offered by the CITI Program</u> in order to receive IRB approval for research projects. In this context, "researchers" include anyone associated with the project, not just the principal investigator. This training must be completed <u>at least once every three years</u>.

There are two versions of initial HSR training offered: Social-Behavioral-Educational (SBE) Comprehensive and Biomedical (Biomed Comprehensive. All researchers submitting IRB applications must complete the Social-Behavioral-Educational Comprehensive (SBE) training. Researchers conducting physiological or biological research must complete the Biomed training in addition to the SBE training.

Both the Biomed and SBE trainings typically take several hours to complete. Researchers should set aside ample time to complete the training as part of the preparation process for IRB submission.

Once your HSR training certification expires **after three years**, you should complete the refresher course associated with your training. There are several refresher courses, numbered sequentially (e.g., Biomed Refresher 1, Biomed Refresher 2). You should complete Refresher 1 after your initial training expires, Refresher 2 three years after completing Refresher 1, and so on.

D. Confidentiality

The RIO or other University official receiving allegations of Research misconduct shall: (1) limit disclosure of the identity of respondents and complainants (and witnesses, when appropriate) to those who need to know in order to carry out a thorough, competent, objective and fair Research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a Research misconduct proceeding. Written confidentiality agreements or other mechanisms should be used to ensure that the recipient does not make any further disclosure of identifying information.

E. Protecting complainants, witnesses, and other participants

University members may not retaliate in any way against complainants, witnesses, or other participants. University members should immediately report any alleged or apparent retaliation against complainants, witnesses or other participants to the RIO or other appropriate University official, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

F. Protecting the Respondent

As requested, and as appropriate, the RIO and other University officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in Research Integrity, but against whom no finding of Research misconduct is made.

During the Research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 (when applicable) and University policy. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice.

G. Interim Administrative Actions and Notifying ORI of Special Circumstances

When alleged Research misconduct involves PHS-supported research, the RIO will review the situation throughout the Research misconduct proceeding to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other University officials and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of

personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a Research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- HHS resources or interests are threatened.
- Research activities should be suspended.
- There is a reasonable indication of possible violations of civil or criminal law.
- Federal action is required to protect the interests of those involved in the Research misconduct proceeding;
- The Research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

IV. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of Research Integrity, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of Research misconduct may be identified and whether the allegation falls within the definition of Research Integrity. An inquiry must be conducted if these criteria are met. Additionally, when the alleged Research misconduct involves PHS-supported research, then it must also be determined whether it is within the jurisdictional criteria of 42 CFR § 93.102(b).

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO 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 RIO 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 RIO determines that the criteria for an inquiry are met, he or she will promptly 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 RIO 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 RIO 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. When PHS-supported research is at issue, the RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of an Inquiry Committee When Appropriate

The RIO may conduct the inquiry or, in consultation with other University officials, the RIO may determine that an inquiry committee is appropriate. If so, the RIO will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. When an inquiry committee is appointed, it 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.

When an inquiry committee is appointed, the RIO will prepare a charge for the committee explaining the time for completion of the inquiry and describing the allegations (and related issues). Additionally, the charge will:

- State the purposes of the inquiry, i.e., (1) to conduct an initial review of evidence, including testimony of the respondent, complainant and key witnesses, (2) to determine whether an investigation is warranted, and (3) <u>not</u> to determine whether Research misconduct definitely occurred or who was responsible;
- State that an investigation is warranted if the inquiry shows: (1) a reasonable basis for concluding that the allegation falls within the definition of Research misconduct(and, for PHS-supported research, is within the jurisdictional criteria of 42 CFR § 93.102(b)); and, (2) the allegation may have substance, based on the inquiry.
- Inform 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, where PHS-supported research is at issue, 42 CFR § 93.309(a).

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

E. Inquiry Process

The RIO (or inquiry committee) will normally interview the complainant, the respondent, and other key witnesses, as well as examine relevant research records and materials. Then, the evidence will be evaluated. The RIO (or the committee, in consultation with the RIO) will decide whether an investigation is warranted based on the criteria in this policy and, where PHS-supported research is at issue, 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 conducting exhaustive interviews and analyses. However, if a 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, when PHS-supported research is at issue, the University shall promptly consult with ORI to determine the next steps that should be taken.

F. Time for Completion

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

V. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of Research Integrity; (3) the basis for recommending or not recommending that the allegations warrant an investigation; (4) any comments on the draft report by the respondent or complainant; and (5) when applicable, the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support.

Modifications should be made as appropriate in consultation with the RIO and the inquiry committee when applicable.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to 42 CFR

Part 93 (when applicable) and the University's policies and procedures on Research Integrity. The University may notify the complainant of the inquiry's outcome and provide relevant portions of the inquiry report for comment within 10 days. However, a confidentiality agreement should be a condition of access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the RIO or inquiry committee may revise the draft report as appropriate and prepare it in final form.

C. University Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination. The RIO will notify those University officials who need to know of the DO's decision.

Notification to ORI

When PHS-supported research is at issue, within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO must provide the following information to ORI upon request: (1) the University 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 to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI, where PHS-supported research was at issue, of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

VI. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether Research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible Research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged Research 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 must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must notify the respondent in writing of the allegations to be investigated, including, within a reasonable amount of time of deciding to pursue them, any new allegations not addressed during the inquiry or in the initial notice of the investigation. Additionally, when PHS-supported research is at issue, the RIO must notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

Prior to notifying respondent of the allegations, the RIO will take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the Research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the University's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The RIO may conduct the investigation or, in consultation with other University officials, the RIO may determine that an investigation committee is appropriate. If so, the RIO will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. When an investigation committee is deemed appropriate, it must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

When an investigation committee is appointed, the RIO will prepare a written charge to the committee that explains the subject matter of the investigation, identifies the respondent, describes the allegations and definition of Research Integrity, and:

- Informs the committee that it must conduct the investigation as prescribed in paragraph D. of this section;
- Informs the committee that it must evaluate the evidence and testimony to determine
 whether, based on a preponderance of the evidence, Research misconduct occurred
 and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed

Research misconduct must find that a preponderance of the evidence establishes that: (1) Research Integrity, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the Research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the Research misconduct intentionally, knowingly, or recklessly; and

 Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and, when PHSsupported research is at issue, 42 CFR § 93.313.

At the investigation committee's first meeting, the RIO will 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 this Policy and, when applicable, 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

D. Investigation Process

The RIO (or the investigation committee) must:

- 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 each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- 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 the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible Research Integrity, and continue the investigation to completion.

E. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and, when PHS-supported research is at issue, sending the final report to ORI. However, if the RIO determines that the

investigation will not be completed within this 120-day period, then the RIO may seek an extension and document the reason(s) for the delay.

When PHS-supported research is at issue, the RIO will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VII. The Investigation Report

A. Elements of the Investigation Report

The RIO (and the investigation committee, when applicable) are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of Research Integrity, including identification of the respondent;
- When applicable, describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of Research misconduct considered in the investigation;
- Includes the University policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of Research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the Research misconduct falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in Research misconduct because of honest error or a difference of opinion; (3) identify whether any publications need correction or retraction; (4) identify the person(s) responsible for the misconduct; and (6) where PHS-supported research is at issue, (i) identify the specific PHS support and (ii) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.
- B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Complainant

On a case-by-case basis, the University may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If the University provides such an opportunity, then the complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the RIO 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 RIO may require that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official

The RIO (or the investigation committee, with the RIO's assistance) will finalize the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the University accepts the investigation report, its findings, and the recommended University actions; and (2) the appropriate University actions in response to the accepted findings of Research Integrity. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. The DO 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. When PHS-supported research is at issue, such determinations should be made after notifying the ORI. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

To the extent provided in other University policy, the respondent may appeal a University taken as a

result of an investigation and DO decision under this Policy. For example, a faculty member respondent may appeal an action taken if it falls under the Faculty Appeals Procedures set forth in Chapter 2 of the Faculty Handbook.

E. Notice to ORI of University Findings and Actions

When PHS-supported research is at issue, unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to ORI: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the University accepts the findings of the investigation report; (3) a statement of whether the University found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

F. Maintaining Records for Review by ORI

When PHS-supported research is at issue, the RIO must maintain and provide to ORI upon request "records of Research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of Research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the Research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of Research misconduct of the University's handling of such an allegation.

VIII. Completion of Cases; Reporting Premature Closures to ORI (Applicable When PHS-Supported Research is at Issue)

The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

IX. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's University employment, by resignation or otherwise, before or after an allegation of possible Research misconduct has been reported, will not preclude or terminate the Research misconduct proceeding or, where applicable, otherwise limit any of the University's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the University receives an allegation of Research Integrity, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the

respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no Research Integrity, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of Research misconduct was previously publicized, and expunging all reference to the Research misconduct allegation from the respondent's personnel file. Any University actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the Research misconduct proceeding and upon its completion, the University and the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of Research misconduct in good faith and of any witnesses and others who participate in Research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of Research misconduct were made in good faith, or whether a witness or other involved acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

X. Policy Review

This Policy shall be reviewed every even numbered calendar year by the Provost in consultation with the Faculty Senate or when necessary due to changes in applicable law.