

Millersville Policy for Responding to
Allegations of Research Misconduct
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MILLERSVILLE POLICY FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

This policy is based upon a "Sample Policy and Procedures for Responding to Research Misconduct Allegations" freely provide by the Office of Research Integrity (ORI) of the US Department of Health and Human Services. The sample policy and procedures complies with the PHS Policies on Research Misconduct (embodied in federal regulations at 42 CFR Part 93) that became effective June 16, 2005.

I. Introduction

A. General Policy

The Millersville University of Pennsylvania community is guided by core principles--scholarship, diversity, integrity and service. Unethical conduct in research and scholarship strike at the heart of two of these principles--scholarship and integrity and undermines the community's commitment to excellence. The purpose of this policy is to provide the members of this academic community a framework for reporting suspected incidents of misconduct as well as investigating and adjudicating cases of misconduct in a fair and consistent manner. It is also intended that any such action be in accordance with applicable federal and state law as well as the Collective Bargaining Agreement (CBA) between the Association of Pennsylvania State College and University Faculties (APSCUF) and the Pennsylvania State System of Higher Education (PASSHE) of which Millersville is a member.

institution. This includes postdoctoral fellows, residents, graduate students, undergraduate students, nurses, technicians, and other staff members. It applies to all individuals engaged in the research enterprise.

2. 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 for proposals for support for biomedical or behavioral research, research training or activities related to that research or re8(or)-3(r)5(e)6(8(or)-3(i -28

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thereto, or has cooperated in good faith with an investigation of such allegation

A. Research Integrity Officer

The Provost will appoint the RIO who will have primary responsibility for

appropriate to carry out a thorough and authoritative evaluation of the evidence;

- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

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resulting action as required by the CBA. The respondent will also be permitted a union representative as outlined within the CBA.

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

In the event of a conflict between this policy and federal and state law, federal and state law shall control. In the event that there is a conflict between these policies and an applicable CBA, the CBA will take precedence.

Institutional employees accused of violations of academic misconduct may consult with an Union Representative to seek advice and bring an Union Representative to interviews or meetings pertaining to the investigation.

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

- A good faith effort from the RIO to notify the respondent in writing when the inquiry is open;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy, or refers to 42 CFR Part 93, if applicable, and a copy of the institution's policies and procedures on research misconduct;
- The Respondent is entitled to be informed of the allegations when an inquiry is opened 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 interview summary and have the corrected summary 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 summary of testimony provided to the witness for correction and have the corrected summary 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 5 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and institutional legal counsel, the Deciding Official may terminate the

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

B. Cooperation with Research Misconduct Proceedings

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

C. Confidentiality

The RIO shall as required by 42 CFR § 93.108, and shall in regards to all other grants (1) limit disclosure of the identity of respondents and complainants 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. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. Written confidentiality agreements shall allow respondents to share information and records with persons necessary to assist the respondent in preparing a response to the complaint. Any parties who

Throughout the research misconduct proceeding, the RIO will be in the situation to determine if there is any threat of harm to public health, federal, state or private funds and equipment, or the integrity of the supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and Grantor pursuant to legal or contractual requirements, take appropriate interim action to protect against any such threats consistent with applicable laws or the CBA. Interim action might include but not be limited to 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 ORB or the Grantor if required to do so by law or contract, 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;
- Grantor 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 action by the Grantor may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

VI.

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. The Committee should consist of less than three (3) individuals and those three (3) can include one or more experts from outside of the University if necessary.

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b) if applicable, or within the jurisdictional criteria of paragraph I. B. 3. of this document if 42 CFR § 93.102(b) does not apply, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and if applicable 42 CFR § 93.309(a).

At the committee's first meeting, the RIO will review the charge with the

with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d) applicable. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses.

However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section

G. 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 twenty (20) 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 twenty(20)-day period. The respondent will be notified of the extension.

VII. 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 misconduct; (3) the PHS alternative grant support including, for example, grant numbers, grant applications, contracts and publications listing PHS or other grantor support; (4) the basis for the determination of support.

(5) days of completion by the Committee and include a copy of or refer to 42 CFR Part 93f applicable and the institution's policies and procedures on research misconduct. A confidentiality agreement should be a condition for access to the report.

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

C. Institutional 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.

2. Notification to ORI

warranted. The purpose of the investigation is to develop a factual record by

committee.

present or available throughout the investigation to advise the committee as needed.

E.

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent;
- Describes and documents the PHS or other Grantor support including, for example, the numbers of any grants that are involved, grant applications,

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In distributing the draft report, or portions thereof, to the respondent, 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 will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing and report to the University President (it) whether the institution accepts the investigation report, its findings and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. 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 notify both the respondent and the complainant in writing.

description of any pending or completed administrative actions ~~in~~ ^{against} the respondent.

F. Maintaining Records for Review by ORI

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. This standard will be used for all grants received by the University. 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 seven (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 or of the institution’s handling of such an allegation.

X. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and significant issues will be pursued diligently. The RIO must notify ORI or another grantor if required to by law or contract, advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent admits 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

Appendix A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93, when applicable.
- Complies with its written policies and procedures and the requirements of 42 CFR, Part 93 when applicable
- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. This criteria applies to all Federal and non-Federal grants as well.

II. Notice and Reporting to ORI and Cooperation with ORI or alternative Grantor, if applicable

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI or as required by any grantor.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93 if applicable, or fulfill any reporting requirements outlined by any Grantor.
- Notifies ORI or other Grantor immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS or other Grantor's resources or interests are threatened, research activities should be suspended, there is 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

institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI or other Grantor if required by law or contract with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within five(5) calendar days of the date on which the finding is made.
- Notifies ORI or other Grantor if required by law or contract of the decision to begin an investigation on or before the date the investigation begins.
- Within sixty (60) days of beginning an investigation, or such additional days as may be granted by ORI or other Grantor if required by law or contract, provides ORI or other Grantor with the investigation report, a statement of whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- Seeks advance ORI approval or other Grantor approval if required by law or contract if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the investigation's findings do not support a finding of research misconduct.
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- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including refusal to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeping the Deciding Official (DO) University President, University Legal Counsel and others who need

sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.
- At the time of, or before beginning the inquiry, making good faith effort to notify the respondent in writing, if the respondent is known.
- On or before the date on which the respondent is notified, or the inquiry begins,

- Prior to notifying respondent of the allegations, taking 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.
- In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.
- Preparing a charge for the investigation committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93, if applicable.
- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording and transcribing those interviews.
- Being available or present throughout the investigation to advise the committee as needed.
- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) makes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews each respondent, complainant, and any other available person who has been reasonably identified as having information regarding relevant aspects of the investigation, including witnesses identified by the respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the records of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.
- Upon determining that the investigation cannot be completed within ~~60~~ calendar

period that includes a statement of the reasons for the extension. Other Grantor if required by law or contract. If the extension is granted, the RIO will file periodic progress reports with ORI or other Grantor if required by law or contract.

- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93.101, applicable, and the institution's policies and procedures, sending the respondent a copy of the draft report for his/her comment within thirty (30) days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent and ensuring that the comments are included and considered in the final investigation report.
- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.
- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.
- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI or other Grantor if required by law or contract, within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.
- Maintaining and providing to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.