



Policy and Procedures for Responding to Allegations of Research Misconduct



Policy and Procedures for Responding to Allegations of Research Misconduct



TABLE OF CONTENTS

I.	INTRODUCTION	5
A.	Purpose of the Policy	5
B.	Scope	5
II.	DEFINITIONS	6
III.	RIGHTS AND RESPONSIBILITIES	7
A.	Research Integrity Officer (RIO)	7
B.	Complainant	8
C.	Respondent	8-9
D.	Deciding Official	9
E.	Interviews During Research Misconduct Proceedings.....	9-10
IV.	GENERAL POLICIES AND PRINCIPLES	11-13
A.	Responsibility to Report Misconduct	11
B.	Cooperation with Research Misconduct Proceedings	11
C.	Confidentiality	11-12
D.	Protecting Complainants, Witnesses, and Committee Members	12
E.	Protecting the Respondent	13
F.	Interim Administrative and Notifying ORI of Special Circumstances	13
V.	CONDUCTING THE ASSESSMENT AND INQUIRY	14-17
A.	Assessment of Allegations	14-15
B.	Initiation and Purpose of the Inquiry	15
C.	Notice to Respondent; Sequestration of Research Records	15
D.	Appointment of the Inquiry Committee	15
E.	Charge to the Committee and First Meeting	16-17
F.	Inquiry Process	17
G.	Time for Completion	17
VI.	THE INQUIRY REPORT.....	18
A.	Elements of the Inquiry Report	18
B.	Notification to the Respondent and Opportunity to Comment	18
C.	Institutional Decision and Notification	19
1.	Determination by the Deciding Official	19
2.	Notification to the Office of Research Integrity (ORI)	19
3.	Documentation of Non-Investigation Decision	19
D.	Institutional Records.....	19-22

Policy and Procedures for Responding to Allegations of Research Misconduct



VII.	CONDUCTING THE INVESTIGATION	22-29
A.	Initiation and Purpose.....	22
B.	Notification to ORI and Respondent; Securement of Research Records	22-23
C.	Constitution of the Investigation Committee	23
D.	Mandate and Inaugural Meeting of the Committee	23
1.	Mandate to the Committee	23-24
2.	Inaugural Meeting	24
E.	Investigation Process	24-25
F.	Time for Completion	25
G.	Pursuit of Leads During the Investigation.....	25-29
VIII.	THE INVESTIGATION REPORT.....	29-36
A.	Elements of the Investigation Report	29-30
B.	Comments on the Draft Report and Access to Evidence	30
1.	Respondent	30
2.	Complainant	30
3.	Confidentiality	30
C.	Decision by Deciding Official	31
D.	Appeals	31-32
E.	Notice to ORI of Institutional Findings and Actions	32
F.	Maintenance of Records for ORI Review	33-36
IX.	COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO ORI	36
X.	INSTITUTIONAL ADMINISTRATIVE ACTIONS	37
XI.	OTHER CONSIDERATIONS	37-47
A.	Termination or Resignation Before Completion of Inquiry or Investigation	37
B.	Restoration of the Respondent's Reputation	37-38
C.	Protection of the Complainant, Witness, and Committee Members	38
D.	Allegations Not Made in Good Faith	38
E.	Honest Error in Research Misconduct Proceedings.....	38
1.	Purpose.....	38
2.	Definition and Regulatory Context.....	39
3.	Consideration of Honest Error.....	39
4.	Evaluation of Evidence.....	40-41
5.	Documentation.....	41

Policy and Procedures for Responding to Allegations of Research Misconduct



F.	Respondent Admissions and Settlement in Research Misconduct Proceedings...	41-45
G.	Research Misconduct Allegations Involving Multiple Institutions	45-47
XII.	RESEARCH INTEGRITY ASSURANCE AND SUBAWARD COMPLIANCE	47-49
A.	Research Integrity Assurance	47
B.	Maintenance of an Active Assurance.....	48
C.	Annual Reporting Requirements.....	48
D.	Applicability to Subawardees.....	48-49
E.	Establishment of a Research Integrity Assurance by Subawardee.....	49
F.	Small Institution Considerations.....	49
G.	Institutional Cooperation with Federal Oversight.....	49
XIII.	COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO ORI.....	50
	PERTINENT SECTIONS OF 42 CFR PART 93 (2024).....	50-52
	APPENDIX A (RESEARCH INTEGRITY OFFICER RESPONSIBILITIES)	53-56
I.	General Responsibilities	53
II.	Notice, Reporting, and Collaboration with ORI	53-54
III.	Research Misconduct Proceedings	54-
a.	General Oversight	54
b.	Allegation Receipt and Assessment	55
c.	Inquiry Proceedings	55
d.	Investigation Proceedings	55-56

Policy and Procedures for Responding to Allegations of Research Misconduct



I. INTRODUCTION

A. PURPOSE OF THE POLICY

The purpose of this policy and its accompanying procedures is to outline the University of Maryland Eastern Shore's commitment to upholding the standards set forth by the Public Health Service (PHS) Policies on Research Misconduct, as outlined in 42 CFR Part 93. This policy applies to instances of research misconduct, including fabrication, falsification, or plagiarism, occurring within the context of proposing, conducting, or reviewing research, as well as in the reporting of research findings.

This policy specifically covers individuals who, at the time of the alleged misconduct, were employed by, served as agents of, or were affiliated through contract or agreement with the university. Additionally, it pertains to activities supported by PHS funding in biomedical or behavioral research, research training, or related activities such as operating tissue and data banks, and disseminating research information. This encompasses applications or proposals submitted for PHS support, as well as instances of plagiarism involving research records produced during PHS-supported endeavors.

It's important to note that this policy does not address disputes related to authorship or collaboration, and it is applicable only to allegations of research misconduct reported within six years of the date the institution or the Department of Health and Human Services (HHS) receives the allegation. However, exceptions may apply based on subsequent use, public health or safety concerns, and grandfather clauses outlined in 42 CFR § 93.105(b).

B. SCOPE

This policy and procedure statement excludes authorship or collaboration disputes. It solely addresses allegations of research misconduct within six years of the institution or

HHS receiving the claim, with considerations for subsequent use, public health or safety, and exceptions outlined in 42 CFR § 93.105(b).

This policy applies to all research misconduct allegations involving applications, proposals, or activities supported by the Public Health Service (PHS), including research conducted by the University of Maryland Eastern Shore as a primary recipient of PHS funding and research conducted under subawards or other pass-through funding arrangements. In accordance with the requirements of Public Health Service Policies on Research Misconduct (42 CFR Part 93), all institutions receiving PHS support, including subrecipient institutions, must maintain an active research integrity assurance with the Office of Research Integrity.

Policy and Procedures for Responding to Allegations of Research Misconduct



II. DEFINITIONS

Complainant Person who in good faith makes an allegation of scientific research misconduct.

Deciding Official (DO) Deciding Official (DO) refers to the institutional figure who renders final judgments on accusations of research misconduct and any resulting institutional actions. The DO is distinct from the Research Integrity Officer (RIO) and must not have been directly involved in the institution's prior inquiry, investigation, or assessment of allegations. However, appointing someone to assess such allegations or serve on an inquiry/investigation committee does not constitute direct prior involvement.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Integrity Officer (RIO) is the institutional representative tasked with: (1) evaluating allegations of research misconduct to ascertain if they meet the criteria outlined in 42 CFR Part 93 and necessitate an inquiry based on their credibility and specificity; (2) supervising inquiries and investigations; and (3) fulfilling other duties outlined in this policy.

Research misconduct under 42 CFR §93.103 means fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research results. Research misconduct does not include honest error or differences of opinion.

Respondent is the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding" (42 C.F.R. § 93.225).

Policy and Procedures for Responding to Allegations of Research Misconduct



III. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer (RIO)

The University of Maryland Eastern Shore's designated institutional official will appoint the Research Integrity Officer (RIO), who will play a pivotal role in implementing the institution's policies and procedures concerning research misconduct. The detailed responsibilities of the RIO are outlined in Appendix A. These duties encompass various aspects of research misconduct proceedings, including:

- Providing confidential consultation to individuals unsure about reporting research misconduct allegations.
- Receiving and assessing allegations of research misconduct to determine if they warrant an inquiry.
- Taking interim action and notifying the appropriate authorities of any special circumstances.
- Safeguarding research data and evidence relevant to allegations securely and in compliance with policies and regulations.
- Ensuring confidentiality for all parties involved in the misconduct proceedings as mandated by relevant laws and institutional policies.
- Notifying respondents and affording them opportunities to review, comment, and respond to allegations and evidence.
- Informing respondents, complainants, and witnesses about procedural steps throughout the misconduct proceedings.
- Appointing qualified individuals to serve on inquiry and investigation committees and addressing any conflicts of interest.
- Taking measures to protect the positions and reputations of complainants, witnesses, and committee members from potential retaliation.
- Keeping relevant parties informed of the progress of the misconduct review.
- Fulfilling reporting obligations to external agencies such as the ORI.
- Ensuring enforcement of administrative actions and notifying relevant parties of such actions.
- Maintaining comprehensive records of the misconduct proceedings and making them available to the ORI as required.

Policy and Procedures for Responding to Allegations of Research Misconduct



B. Complainant

The individual lodging the complaint bears the responsibility of making allegations in good faith, maintaining confidentiality, and fully cooperating with the inquiry and subsequent investigation. It is recommended that the complainant be interviewed during the inquiry phase and provided with a transcript or recording of the interview for review and correction. Furthermore, it is imperative that the complainant is interviewed as part of the investigation process and given the opportunity to review and correct the transcript or recording of the interview. Additionally, as per institutional policy or on a case-by-case basis, the institution may furnish the complainant with relevant sections of the inquiry report within a timeframe allowing the inquiry's completion within 60 days of its commencement, as well as the draft investigation report or pertinent sections thereof. The institution is mandated to stipulate that any feedback on the draft investigation report must be submitted within 30 days of the complainant's receipt of the draft report. All comments provided by the complainant on the draft investigation report must be duly considered and included in the final investigation report.

C. Respondent

The individual identified as the respondent bears the responsibility of upholding confidentiality and fully cooperating with both the inquiry and subsequent investigation. The respondent is entitled to the following:

- A written notification from the Responsible Institutional Official (RIO) in good faith at the outset or prior to commencing an inquiry.
- An opportunity to provide comments on the inquiry report, with the assurance that these comments will be appended to the report.
- Notification of the inquiry's outcome and receipt of a comprehensive inquiry report containing references to 42 CFR Part 93 and the institution's research misconduct policies and procedures.
- Written notification of the allegations to be investigated within a reasonable timeframe following the determination that an investigation is warranted, including any new allegations identified after the initial notice.
- Participation in an interview during the investigation, with the opportunity to rectify any inaccuracies in the recording or transcript, ensuring their inclusion in the investigation's record.
- The right to request interviews with any witnesses reasonably identified as possessing relevant information, with provided recordings or transcripts subject to correction by the witness and inclusion in the investigation record.

Policy and Procedures for Responding to Allegations of Research Misconduct



- Provision of a copy of the draft investigation report along with access to the evidence supporting it, and notification that any comments must be submitted within 30 days, with an assurance that these comments will be considered and addressed in the final report.

Additionally, the respondent should be afforded the opportunity to admit to any research misconduct and, with guidance from the RIO or other institutional officials, the Deciding Official may choose to terminate the institution's review of the allegation upon approval of the admission and any proposed settlement by the Office of Research Integrity (ORI).

D. Deciding Official

Upon receiving the inquiry report, the Deciding Official (DO) will collaborate with the Responsible Institutional Official (RIO) and/or other relevant institutional authorities to determine whether an investigation is warranted according to the criteria outlined in 42 CFR § 93.307(d). Any decision affirming the necessity for an investigation must be documented in writing by the DO and promptly submitted to the Office of Research Integrity (ORI), accompanied by a copy of the inquiry report fulfilling the specifications of 42 CFR § 93.309, within a 30-day timeframe from the decision date. In cases where an investigation is deemed unnecessary, the DO and RIO will ensure meticulous retention of comprehensive documentation pertaining to the inquiry for a minimum duration of 7 years following its conclusion. This measure enables ORI to evaluate the rationale behind the institution's decision against conducting an investigation.

Subsequently, upon receipt of the investigation report, the DO, in consultation with the RIO and/or other pertinent institutional figures, will assess the extent to which the institution acknowledges the investigation findings and, if instances of research misconduct are confirmed, determine suitable institutional administrative actions, if any. The DO is responsible for guaranteeing the submission of the final investigation report, the DO's conclusions, and a summary of any ongoing or concluded administrative measures to ORI, in accordance with the obligations stipulated in 42 CFR § 93.315.

E. Interviews During Research Misconduct Proceedings

In accordance with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93), **UMES** may conduct interviews as part of the inquiry and investigation phases of research misconduct proceedings in order to obtain information relevant to the review of allegations.

Policy and Procedures for Responding to Allegations of Research Misconduct



1. Interviews During the Inquiry Phase

During the inquiry phase, the University may interview the complainant, respondent, or other individuals who may have information relevant to the allegations. Interviews conducted during the inquiry phase are **not required to be recorded or transcribed**. However, the University may document these interactions as appropriate to maintain an accurate record of the proceedings.

If recordings, transcripts, or written summaries of inquiry interviews are created and relied upon during the research misconduct proceeding, they will become part of the **institutional record**.

2. Interviews During the Investigation Phase

During the investigation phase, the University will **conduct, record, and transcribe interviews** with the respondent, the complainant, and any other individuals reasonably identified as having information relevant to the investigation, including witnesses identified by the respondent.

Individuals interviewed during the investigation will be given an opportunity to **review the transcript of their interview and submit corrections or clarifications** for inclusion in the investigation record.

3. Determination of Formal Interviews

The University has discretion to determine whether a particular interaction constitutes a formal interview for purposes of the research misconduct proceeding. In making this determination, the University may consider factors such as:

- a. Whether the discussion involves information with potential evidentiary value related to the allegations;
- b. Whether the interaction was requested or arranged by the University as part of the proceeding; and
- c. The level of formality associated with the interaction, such as a scheduled meeting conducted for the purpose of gathering information related to the allegation.

Conversations addressing routine procedural matters, scheduling, or general questions about the research misconduct process may not be considered formal interviews.

Policy and Procedures for Responding to Allegations of Research Misconduct



IV. GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct

All members of the University of Maryland Eastern Shore are obligated to promptly report any observed, suspected, or apparent instances of research misconduct to the Responsible Institutional Official (RIO). Additionally, [Option: other designated officials] should also be informed. Individuals who are uncertain whether a suspected incident constitutes research misconduct are encouraged to arrange a meeting or contact the RIO at [contact information] for informal discussion. This may include the option to discuss the matter anonymously and/or hypothetically. If, upon review, the circumstances outlined by the individual do not align with the definition of research misconduct, the RIO will refer the individual or allegation to other relevant offices or officials tasked with addressing such issues.

Furthermore, institutional members are assured the opportunity to engage in confidential discussions and consultations regarding concerns of potential misconduct with the RIO [Option: other designated officials]. They will receive guidance on the appropriate procedures for reporting allegations at any point in time.

B. Cooperation with Research Misconduct Proceedings

All individuals associated with the University of Maryland Eastern Shore are expected to collaborate with the Responsible Institutional Official (RIO) and other relevant institutional personnel during the examination of allegations and the execution of inquiries and investigations. This obligation extends to all members, including those implicated in the allegations, who are required to furnish any pertinent evidence regarding research misconduct allegations to the RIO or other designated institutional authorities.

C. Confidentiality

In compliance with 42 CFR § 93.108, the Responsible Institutional Official (RIO) is mandated to: **(1) Limit Disclosure of Identities.** Restrict the disclosure of the identities of respondents, complainants, and witnesses to individuals who have a legitimate **need to know** in order to carry out a thorough, competent, objective, and fair research misconduct proceeding, and as permitted by law. Individuals who may have a need to

Policy and Procedures for Responding to Allegations of Research Misconduct



know may include appropriate institutional officials, oversight committees, journals, editors, publishers, co-authors, collaborating institutions, or funding agencies when disclosure is necessary to address issues related to the integrity of the research record.

(2) Protect Research Subjects and Sensitive Information. Except as otherwise required by law, limit the disclosure of any records or evidence from which research subjects might be identified to those persons directly involved in conducting the research misconduct proceeding. All research records and evidence obtained during a research misconduct proceeding must be maintained in a **secure manner**, and access must be limited to authorized individuals. **(3) Maintain Confidential Handling of Records.** Ensure that all sequestered research records and other evidence are handled and stored securely throughout the research misconduct proceeding. The RIO may use written confidentiality agreements or other appropriate mechanisms to prevent unauthorized disclosure of identifying or sensitive information. **(4) Disclosure to Oversight Authorities.** Notwithstanding the limitations described above, the University must provide relevant records and the identities of respondents, complainants, and other appropriate individuals to the **U.S. Department of Health and Human Services Office of Research Integrity** when required for oversight review or as otherwise required by law. **(5) Correction of Research Record.** Nothing in this policy prevents the University from taking appropriate steps to manage or correct the research record, including notifying journals, publishers, collaborators, or funding agencies if published or reported data may be unreliable. Such actions may occur during or after a research misconduct proceeding, including when errors are determined to result from honest error. **(6) Protection from Retaliation.** Consistent with federal requirements, the University will take all reasonable and practical steps to protect the positions and reputations of **good-faith complainants, witnesses, and committee members**, and to protect these individuals from retaliation by respondents or other institutional members.

D. Protecting complainants, witnesses, and committee members

Institutional members are prohibited from engaging in any form of retaliation against complainants, witnesses, or committee members. It is imperative that institutional members promptly report any suspected or apparent retaliation against complainants, witnesses, or committee members to the Responsible Institutional Official (RIO). The RIO will thoroughly investigate the matter and, where deemed necessary, take all feasible measures to address and prevent any potential or actual retaliation. Additionally, the RIO will endeavor to safeguard and restore the position and reputation of the individual subjected to retaliation.

Policy and Procedures for Responding to Allegations of Research Misconduct



E. Protecting the Respondent

Upon request and as deemed appropriate, the Responsible Institutional Official (RIO) and other relevant institutional figures are committed to employing all reasonable and feasible measures to safeguard or restore the reputation of individuals accused of research misconduct but not found guilty of such misconduct.

Throughout the research misconduct process, the RIO is tasked with ensuring that respondents are afforded all notifications and opportunities outlined in 42 CFR Part 93 and the institution's policies and procedures. Respondents have the right to seek counsel from legal representatives or non-legal personal advisors (who are not directly involved as principals or witnesses in the case) for guidance and support. Furthermore, respondents may be accompanied by their chosen counsel or personal advisor to interviews or meetings pertaining to the case.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceedings, the Responsible Institutional Official (RIO) will assess the situation to ascertain any potential risks to public health, federal funding and equipment, or the integrity of the Public Health Service (PHS) supported research process. Should such risks be identified, the RIO, in collaboration with other institutional authorities and the Office of Research Integrity (ORI), will implement suitable interim measures to mitigate these risks. These interim measures may include heightened monitoring of research activities and the management of federal funds and equipment, reassignment of personnel or responsibilities related to federal funds and equipment, intensified scrutiny of research data and outcomes, or postponement of publication. At any stage of the research misconduct proceedings, the RIO is obliged to promptly inform ORI if there are indications of any of the following conditions:

- Imminent threats to public health or safety, necessitating immediate protection of human or animal subjects;
- Risks to Department of Health and Human Services (HHS) resources or interests;
- Recommendations for suspension of research activities;
- Reasonable suspicion of potential violations of civil or criminal law;
- Requirement for federal intervention to safeguard the interests of parties involved in the research misconduct proceedings;
- Risk of premature public disclosure of the proceedings, requiring HHS intervention to preserve evidence and uphold the rights of involved parties; or
- Necessity to inform the research community or public.

Policy and Procedures for Responding to Allegations of Research Misconduct



V. CONDUCTING THE ASSESSMENT AND INQUIRY

A. Assessment of Allegations

Upon receipt of an allegation of research misconduct, the Responsible Institutional Official (RIO) will promptly conduct an assessment to determine whether the allegation warrants the initiation of an inquiry. The assessment involves a review of readily accessible information relevant to the allegation and is intended to determine whether the allegation meets the criteria required to proceed to an inquiry.

During the assessment, the RIO will evaluate the credibility and specificity of the allegation to determine whether potential evidence of research misconduct may be identified. Additionally, the RIO will ascertain whether the allegation falls within the jurisdictional criteria outlined in 42 CFR §93.102(b) and aligns with the definition of research misconduct under 42 CFR §93.103. If these criteria are met, an inquiry must be initiated.

The assessment should be conducted promptly and, whenever possible, completed within approximately one week of receiving the allegation. During this stage, the RIO may review submitted documentation and, when appropriate, seek clarification from the complainant. The assessment phase does not normally involve interviewing the respondent.

If the allegation concerns matters outside the definition of research misconduct—such as harassment, financial misconduct, or violations involving the protection of human or animal research subjects—the RIO will refer the matter to the appropriate institutional office or authority for further review.

Throughout the assessment process, the RIO will maintain the confidentiality of the complainant, respondent, and research records to the extent permitted by law and institutional policy.

1. Purpose of the Assessment

The purpose of the assessment is to determine whether an allegation of research misconduct warrants the initiation of an inquiry in accordance with applicable federal regulations.

Policy and Procedures for Responding to Allegations of Research Misconduct



2. Criteria for Initiating an Inquiry

An inquiry will be initiated if the RIO determines that the allegation meets the following criteria:

3. Definition of Research Misconduct

The allegation falls within the definition of research misconduct under 42 CFR §93.103, which includes fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research results. Research misconduct does not include honest error or differences of opinion.

4. Applicability of Federal Regulations

The allegation meets the applicability criteria of 42 CFR §93.102 by involving Public Health Service (PHS)–supported biomedical or behavioral research, research training, or related activities.

5. Credibility and Specificity

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

If these criteria are met, the RIO will promptly initiate an inquiry. The RIO will document the assessment and the basis for determining whether the allegation meets these criteria. Assessment documentation will become part of the institutional record and will be retained in accordance with applicable federal record retention requirements.

B. Initiation and Purpose of the Inquiry

Upon confirming that the prerequisites for an inquiry are satisfied, the Responsible Institutional Official (RIO) will promptly commence the inquiry proceedings. The inquiry serves to undertake an initial examination of the existing evidence to decide whether an investigation is warranted. It is important to note that an inquiry does not necessitate a comprehensive evaluation of all evidence pertaining to the allegation.

Policy and Procedures for Responding to Allegations of Research Misconduct



C. Notice to Respondent; Sequestration of Research Records

Prior to initiating an inquiry, the Responsible Institutional Official (RIO) is obligated to make a sincere attempt to inform the respondent in writing, if their identity is known. If additional respondents are identified during the inquiry, they must also be notified in writing. Before notifying the respondent or commencing the inquiry, whichever occurs earlier, the RIO must undertake all reasonable and practical measures to secure custody of all necessary research records and evidence. This involves inventorying and securely sequestering the records and evidence. In cases where scientific instruments are shared by multiple users, custody may be restricted to copies of the data or evidence from these instruments, provided that these copies hold substantially equivalent evidentiary value. The RIO retains the option to seek advice and assistance from the U.S. Department of Health and Human Services Office of Research Integrity regarding sequestration of records or other procedural matters.

D. Appointment of the Inquiry Committee

Following the initiation of the inquiry, the Responsible Institutional Official (RIO), in consultation with relevant institutional authorities, will promptly establish an inquiry committee and designate a committee chair. The composition of the inquiry committee must adhere to specific criteria: its members must be free from unresolved personal, professional, or financial conflicts of interest with any parties involved in the inquiry. Additionally, the committee should include individuals possessing the requisite scientific expertise to assess the evidence and issues pertinent to the allegation, conduct interviews with key individuals, and oversee the inquiry process.

E. Charge to the Committee and First Meeting

The RIO will prepare a written charge to the inquiry committee, that includes:

- Details of the allegations and any associated issues uncovered during the initial assessment.
- The committee's responsibility to conduct a preliminary evaluation of the evidence to determine whether an investigation is warranted.
- The criteria for determining whether an investigation is warranted
- A timeframe for completing the inquiry.
- The committee's responsibility to prepare or oversee the preparation of a written inquiry report.

Policy and Procedures for Responding to Allegations of Research Misconduct



During the committee's inaugural meeting, the RIO will review the charge, discuss the allegations and procedures, assist in organizing the inquiry plans, and respond to questions from the committee. The RIO will remain accessible throughout the inquiry to provide procedural guidance.

F. Inquiry Process

The inquiry committee will typically conduct interviews with the complainant, respondent, and key witnesses, in addition to examining pertinent research records and materials. Subsequently, the committee will assess the gathered evidence, including testimonies obtained during the inquiry process. Following consultation with the RIO, committee members will determine whether an investigation is warranted, adhering to the criteria outlined in this policy and 42 CFR § 93.307(d).

It's important to note that the inquiry's scope generally does not entail definitive determinations of misconduct, identification of responsible parties, or exhaustive interviews and analyses. However, if the respondent makes a legally sufficient admission of research misconduct, a determination of misconduct may be reached during the inquiry phase provided all pertinent issues are resolved. In such instances, the institution will promptly engage with ORI to establish the subsequent course of action. Refer to Section IX for further details.

G. Time for Completion

The inquiry process, encompassing the drafting of the final inquiry report and the decision-making by the DO regarding the necessity of an investigation, should be concluded within **60 calendar days** of commencing the inquiry, unless the RIO deems that specific circumstances justify an extension. Should an extension be sanctioned by the RIO, the inquiry documentation must incorporate reasoning for surpassing the initial 60-day timeframe. The respondent will be informed of any granted extension.

Policy and Procedures for Responding to Allegations of Research Misconduct



VI. THE INQUIRY REPORT

A. Elements of the Inquiry Report

A formal inquiry report needs to be compiled, encompassing the following details: (1) identification of the respondent, including their name and position; (2) a comprehensive outline of the accusations regarding research misconduct; (3) documentation of PHS support, such as grant numbers, applications, contracts, and publications with PHS backing; (4) rationale behind recommending or not recommending further investigation into the allegations; and (5) any feedback received on the preliminary report from both the respondent and the complainant.

Legal counsel affiliated with the institution should assess the report for its legal adequacy, making necessary adjustments in collaboration with the Research Integrity Officer (RIO) and the inquiry committee. An alternative approach suggests the inclusion of additional elements such as the identities and roles of committee members and experts involved in the inquiry, a synopsis of the inquiry methodology employed, a catalog of research documents scrutinized, summaries of conducted interviews, and proposed actions if an investigation isn't deemed necessary.

B. Notification to the Respondent and Opportunity to Comment

The Research Integrity Officer (RIO) is responsible for informing the respondent of the inquiry's findings regarding the need for an investigation. This notification shall include provision of the draft inquiry report for feedback within a suggested timeframe of 10 days. Additionally, the RIO must furnish or refer to 42 CFR Part 93 along with the institution's policies and procedures on research misconduct.

Alternatively, the institution may inform the complainant of the inquiry's outcome regarding the necessity for an investigation. Relevant sections of the inquiry report may be shared with the complainant for commentary within a suggested timeframe of 10 days. Access to the report should be subject to a confidentiality agreement.

Any comments submitted by either the respondent or the complainant will be appended to the final inquiry report. Upon review of these comments, the inquiry committee may revise the draft report as necessary and prepare the final version. Subsequently, the committee will submit the finalized report to the RIO.

Policy and Procedures for Responding to Allegations of Research Misconduct



C. Institutional Decision and Notification

1. Determination by the Deciding Official

Upon receiving the final inquiry report and any accompanying comments, the Research Integrity Officer (RIO) will forward these to the Deciding Official (DO) for a written decision on whether an investigation is merited. The inquiry process concludes upon the DO's issuance of this determination.

2. Notification to the Office of Research Integrity (ORI)

Within **30 calendar days** of the DO's decision to proceed with an investigation, the RIO will furnish the ORI with the written decision and a copy of the inquiry report. Additionally, the RIO will inform relevant institutional authorities of the DO's decision. Upon request, the RIO must provide ORI with: (1) institutional procedural guidelines for conducting the inquiry, (2) pertinent research materials, such as records, evidence, interview transcripts or recordings, and relevant documents, and (3) the specific charges to be addressed during the investigation.

3. Documentation of Non-Investigation Decision

In cases where the DO determines that an investigation is unwarranted, the RIO will retain detailed documentation of the inquiry for seven years following its closure. This documentation will sufficiently explain the rationale for not initiating an investigation, facilitating future assessments by ORI. Upon request, these documents must be made available to ORI or other authorized personnel from the Department of Health and Human Services (HHS).

D. Institutional Records

1. Institutional Record of Research Misconduct Proceedings

In accordance with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93), UMES will maintain an institutional record for each research misconduct proceeding. The institutional record consists of the documentation compiled or generated by the University during the assessment, inquiry, investigation, and resolution of an allegation of research misconduct. The institutional record serves as the official documentation of the University's actions and findings and may be reviewed by the U.S. Department of Health and

Policy and Procedures for Responding to Allegations of Research Misconduct



Human Services Office of Research Integrity as part of its oversight responsibilities.

Consistent with 42 CFR §93.220, the institutional record includes the materials that the University compiled or relied upon during the research misconduct proceeding, including but not limited to:

- a. Assessment documentation, including records supporting the determination of whether an inquiry was warranted.
- b. Inquiry records, if an inquiry is conducted, including:
 - The inquiry report;
 - Research records and other evidence reviewed during the inquiry;
 - Transcripts or summaries of interviews conducted during the inquiry;
 - Information provided by the respondent; and
 - Documentation supporting any decision not to proceed to an investigation.
- c. Investigation records, if an investigation is conducted, including:
 - The investigation report;
 - Research records and other evidence considered during the investigation;
 - Transcripts of interviews conducted during the investigation; and
 - Information provided by the respondent.
- d. Decisions of the Institutional Deciding Official, including written determinations regarding research misconduct findings.
- e. Records of any institutional appeal, including all documentation related to the appeal and its outcome.
- f. In addition, the institutional record will include:
 - A comprehensive index listing all research records and evidence compiled during the research misconduct proceeding that were considered or relied upon by the University; and
 - A general description of records that were sequestered but not relied upon during the proceeding.

Policy and Procedures for Responding to Allegations of Research Misconduct



2. Transmission of Records to ORI

UMES will provide documentation from the institutional record to ORI as required under federal regulations.

- a. Assessment stage: Documentation of the assessment will be provided to ORI upon request.
- b. Inquiry stage:
 - If the University determines that an investigation is warranted, a copy of the inquiry report will be provided to ORI **within 30 days of that determination.**
 - If the University determines that an investigation is not warranted, the University will maintain documentation supporting that decision and provide it to ORI upon request.
- c. Investigation stage:

After the Institutional Deciding Official makes a final determination regarding research misconduct findings, UMES will transmit the complete institutional record to ORI.
- d. Appeals:

If a respondent appeals the University's finding of research misconduct or related institutional actions, UMES will notify ORI and provide the complete record of the appeal once the appeal process is concluded.

At any time, UMES will provide research records, evidence, and other relevant documents to ORI upon request.

3. ORI Oversight Review

ORI may review the institutional record to determine whether the University's research misconduct proceedings were conducted in accordance with federal regulations and institutional policy. ORI may request additional documentation, clarification, or revisions to the institutional record if necessary.

During its oversight review, ORI may also request that additional allegations be addressed or that respondents be given the opportunity to respond to new information included in the record.

Policy and Procedures for Responding to Allegations of Research Misconduct



4. Maintenance and Retention of Institutional Records

UMES will maintain the institutional record and all sequestered evidence, including physical objects and research materials, in a secure manner.

Consistent with federal regulations, these records will be retained for **at least seven (7) years** after completion of the institutional proceeding or any related proceeding conducted by HHS, whichever is later, unless custody of the records has been transferred to HHS or ORI directs otherwise in writing.

Upon request, UMES will transfer custody of or provide copies of the institutional record and any sequestered evidence to ORI for purposes of oversight review or administrative proceedings.

VII. CONDUCTING THE INVESTIGATION

A. Initiation and Purpose

The investigation shall commence within 30 calendar days subsequent to the Deciding Official's determination that an investigation is justified. Its primary objective is to meticulously scrutinize the allegations, delve into the evidence comprehensively, and compile factual findings regarding the occurrence, extent, and perpetrators of any potential research misconduct. Additionally, the investigation will ascertain whether there exist further instances of potential research misconduct, warranting an expanded inquiry beyond the initial allegations. This is particularly crucial in cases where the alleged misconduct involves clinical trials, poses potential harm to human subjects or the public, or impacts research forming the foundation of public policy, clinical practice, or public health strategies. Per 42 CFR § 93.313, the investigation findings must be documented in an investigation report.

B. Notification to ORI and Respondent; Securement of Research Records

Before the investigation commences, the Research Integrity Officer (RIO) is obligated to: (1) inform the Director of the Office of Research Integrity (ORI) about the decision to launch the investigation and furnish ORI with a copy of the inquiry report; and (2) formally notify the respondent of the allegations to be examined. The RIO must also provide written notice to the respondent regarding any new allegations of research misconduct within a reasonable timeframe upon deciding to pursue allegations not addressed during the inquiry or mentioned in the initial notification of the investigation.

Policy and Procedures for Responding to Allegations of Research Misconduct



Furthermore, the RIO shall take all necessary measures to obtain custody of and securely sequester all pertinent research records and evidence required for the research misconduct proceedings, if such sequestration was not previously executed during the inquiry phase. Additional sequestration of records during the investigation may be necessary for various reasons, including the institution's decision to investigate additional allegations not covered during the inquiry or the identification of records during the inquiry process that were not previously secured. The procedures for sequestration during the investigation shall mirror those applied during the inquiry.

C. Constitution of the Investigation Committee

Following the commencement of the investigation, the Research Integrity Officer (RIO), in consultation with appropriate institutional authorities, will promptly appoint an investigation committee and designate its chair. The composition of this committee must ensure that its members do not harbor any unresolved personal, professional, or financial conflicts of interest with individuals involved in the investigation. It is advisable for the committee to include individuals possessing the requisite scientific expertise to assess the evidence and issues pertinent to the allegations, conduct interviews with the respondent and complainant, and oversee the investigation. Some members of the investigation committee may have previously served on the inquiry committee.

D. Mandate and Inaugural Meeting of the Committee

1. Mandate to the Committee

The RIO will outline the focus of the investigation in a written mandate to the committee, which should:

- a. Specify the allegations and associated issues identified during the inquiry.
- b. Identify the respondent.
- c. Instruct the committee to conduct the investigation as outlined in paragraph E of this section.
- d. Define research misconduct.
- e. Direct the committee to assess the evidence and testimonies to determine, by a preponderance of the evidence, whether research misconduct occurred, its type, extent, and the responsible party.
- f. Instruct the committee that to establish respondent's involvement in research misconduct, it must find that: (1) research misconduct, as per this policy, indeed occurred (the burden of proof for any affirmative defenses, such as honest error or difference of opinion, rests with the

Policy and Procedures for Responding to Allegations of Research Misconduct



- g. respondent); (2) the research misconduct represents a significant deviation from accepted practices within the relevant research community; and (3) the respondent intentionally, knowingly, or recklessly committed the research misconduct.
- h. Direct the committee to prepare or oversee the preparation of a written investigation report meeting the requirements of this policy and 42 CFR § 93.313.
- i. Direct the committee to diligently pursue all significant issues and leads identified during the investigation that are determined to be relevant to the allegations under review, including any evidence of additional instances of possible research misconduct, and to recommend expansion of the investigation when warranted, consistent with **Section VII.G (Pursuit of Leads During the Investigation)** and applicable provisions of **Public Health Service Policies on Research Misconduct (42 CFR Part 93)**.

2. Inaugural Meeting

The Research Integrity Officer (RIO) will call for the initial gathering of the investigation committee to examine the charge, the inquiry report, and the designated protocols and benchmarks for conducting the investigation. This includes emphasizing the importance of confidentiality and devising a tailored investigation plan. The committee will receive a comprehensive overview of this policy statement and procedures along with 42 CFR Part 93. The RIO will remain present or accessible throughout the investigation to offer guidance to the committee as required.

E. Investigation Process

The investigation committee and the RIO are required to:

- 1. Conduct the investigation diligently, ensuring thorough documentation and examination of all pertinent research records and evidence essential for adjudicating each allegation's merits.
- 2. Endeavor to maintain impartiality and objectivity throughout the investigation process to the fullest extent feasible.

Policy and Procedures for Responding to Allegations of Research Misconduct



3. Interview all relevant parties, including the respondent, complainant, and any individuals with pertinent information identified during the inquiry. Each interview should be recorded or transcribed, with the recording or transcript provided to the interviewee for review and inclusion in the investigation record.
4. Diligently pursue all significant issues and leads identified during the investigation that are determined to be relevant to the allegations under review, including any evidence of additional instances of possible research misconduct, consistent with the requirements described in **Section VII.G (Pursuit of Leads During the Investigation)** and applicable provisions of **Public Health Service Policies on Research Misconduct (42 CFR Part 93)**.

F. Time for Completion

The investigation must conclude within 120 days from its initiation, encompassing the investigation process, drafting the findings report, soliciting feedback on the draft report, and submitting the final report to ORI. In cases where the Research Integrity Officer (RIO) anticipates that the investigation cannot be finalized within this timeframe, they will submit a written extension request to ORI, detailing the reasons for the delay. The RIO will oversee the submission of periodic progress reports to ORI if the extension request is granted and ORI specifies the requirement for such reports.

G. Pursuit of Leads During the Investigation

1. Purpose

The University of Maryland Eastern Shore (UMES) will conduct research misconduct investigations in a thorough, competent, objective, and fair manner in accordance with the requirements of the Public Health Service Policies on Research Misconduct (42 CFR Part 93) issued by the U.S. Department of Health and Human Services.

Federal regulations require institutions conducting research misconduct investigations to diligently pursue all significant issues and leads discovered during the investigation that are determined to be relevant, including any evidence suggesting additional instances of possible research misconduct. Investigations must continue until all relevant issues have been addressed and the investigation is completed.

Policy and Procedures for Responding to Allegations of Research Misconduct



2. Institutional Responsibility to Pursue Leads

During the investigation phase, UMES will pursue all significant issues and leads that may reasonably relate to the allegation(s) under review. This includes evaluating whether evidence suggests additional instances of possible research misconduct beyond the original allegations.

Failure to pursue relevant leads may compromise the effectiveness and integrity of the investigation. Conducting a thorough investigation helps ensure that:

- a. Research misconduct proceedings are conducted with **thoroughness, competence, objectivity, and fairness.**
- b. The investigation sufficiently examines the scope and circumstances of the alleged misconduct.
- c. Evidence identifying the individual(s) responsible for research misconduct is properly evaluated.
- d. Determinations regarding whether misconduct was committed **intentionally, knowingly, or recklessly** are supported by the evidence.
- e. Appropriate institutional actions can be identified and implemented.
- f. Potentially unreliable research findings are identified and addressed to protect the integrity of the scientific record.

3. Identification of Significant Issues or Leads

During the investigation, the Research Integrity Officer (RIO) and the Investigation Committee will review research records and other evidence to determine whether additional allegations or concerns may be relevant to the investigation.

Evidence reviewed may include, but is not limited to:

- a. Grant applications and funding proposals
- b. Published articles and manuscripts
- c. Laboratory records and laboratory notebooks
- d. Raw or processed data
- e. Digital files stored on laboratory computers, hard drives, or other electronic storage devices
- f. Presentation materials, posters, or other research communications

The examination of such materials may reveal patterns or information suggesting that the scope of the investigation should be expanded.



4. Examples of Leads That May Require Expansion of the Investigation

Examples of issues or leads that may warrant further review or expansion of the investigation include, but are not limited to:

a. Patterns of Conduct

Evidence indicating patterns of falsification or fabrication across multiple figures, publications, or grant applications, particularly over an extended period of time.

b. Repeated Data Manipulation or Reuse

Instances where the same type of manipulation or falsification appears repeatedly, such as:

- Reuse and relabeling of western blot panels, microscopy images, or flow cytometry graphs;
- Reuse of portions of images or other source data across different figures or publications;
- Manipulation of reused images or data through relabeling, cropping, rotation, splicing, or other alterations.

c. Repeated Use of Questioned Methods

Situations in which the respondent repeatedly used a methodology or technique that generated the questioned data in multiple experiments, publications, or grant submissions.

d. Evidence That Experiments Were Not Conducted

Evidence suggesting that experiments underlying reported data may not have been performed, such as:

- Lack of laboratory records or research documentation;
- Absence of original data supporting reported results;
- Lack of files on laboratory computers or data storage systems;
- Evidence indicating that the respondent did not utilize required laboratory instruments or facilities needed to produce the reported results.

Policy and Procedures for Responding to Allegations of Research Misconduct



5. Expansion of Allegation

If the investigation identifies evidence suggesting additional instances of research misconduct, UMES may expand the scope of the investigation to include those additional matters.

When new allegations are identified during an investigation:

- a. The respondent will be notified in writing of the additional allegations within a reasonable period of time.
- b. The respondent will be provided an opportunity to respond to the new allegations in accordance with the procedures described in this policy.
- c. The investigation committee will review the additional evidence and incorporate relevant findings into the investigation report.

The institution may also evaluate whether additional individuals may be responsible for the potential misconduct identified during the investigation.

6. Consideration of Time Limitations

In reviewing additional allegations identified during the investigation, UMES will consider the **six-year limitation period** described in **42 CFR § 93.104**, as well as applicable exceptions, including:

- a. The **subsequent use exception**, which applies when a respondent continues to benefit from previously falsified, fabricated, or plagiarized research records through citation, republication, or reuse; and
- b. The **public health or safety exception**, which may apply when alleged research misconduct could have a substantial adverse effect on public health or safety.

The subsequent use exception applies when the respondent uses, republishes, or cites the specific portion of the research record alleged to have been fabricated, falsified, or plagiarized within the six-year period for the respondent's potential benefit, such as in manuscripts, grant applications, progress reports, presentations, or other research communications.

The Research Integrity Officer (RIO) will evaluate the applicability of these exceptions on an allegation-by-allegation basis as part of the institutional assessment process.

When determining that an exception does not apply, UMES will document the basis for that determination in the institutional record.

Policy and Procedures for Responding to Allegations of Research Misconduct



7. Documentation

The Research Integrity Officer (RIO) and Investigation Committee will ensure that the investigation record documents:

- a. Significant issues or leads identified during the investigation;
- b. The steps taken to evaluate those leads;
- c. Any expansion of the scope of the investigation; and
- d. The final determination regarding whether additional research misconduct occurred.

Documentation will be retained in accordance with the record retention requirements established in this policy and federal regulations.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are tasked with composing a written draft report of the investigation, which should:

1. Detail the nature of the research misconduct allegation, including the identification of the respondent. [Option: The respondent's curriculum vitae or resume may be appended for identification purposes.]
2. Document the PHS support comprehensively, encompassing grant numbers, grant applications, contracts, and publications listing PHS support.
3. Outline the specific allegations of research misconduct under scrutiny during the investigation.
4. Include the institutional policies and procedures governing the investigation, unless previously provided to ORI.
5. Summarize and identify the research records and evidence examined, along with any evidence secured but not yet reviewed.
6. Present a series of findings for each allegation of research misconduct identified in the investigation. Each finding statement should:
 - a. Specify whether the research misconduct entailed falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly.

Policy and Procedures for Responding to Allegations of Research Misconduct



- b. Summarize the pertinent facts and analyses supporting the conclusion, taking into account any reasonable explanations put forth by the respondent, including efforts to demonstrate, by a preponderance of evidence, a lack of engagement in research misconduct due to honest error or differences of opinion.
- c. Identify the specific PHS support implicated.
- d. Determine if any publications require correction or retraction.
- e. Identify the individual(s) accountable for the misconduct.
- f. List any ongoing support or known applications or proposals for support pending with non-PHS federal agencies by the respondent.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The Research Integrity Officer (RIO) is required to furnish the respondent with a copy of the preliminary investigation report for review and simultaneously provide either a copy of, or supervised access to, the evidence forming the basis of the report. The respondent is granted a 30-day period from the receipt of the draft report to submit comments to the RIO. These comments from the respondent must be incorporated and taken into account in the final report.

2. Complainant

The Complainant will only receive a copy of the final report at which time they will sign a confidentiality agreement.

3. Confidentiality

When distributing the draft report, or relevant segments thereof, to the respondent, the RIO will clarify the confidentiality terms under which the draft report is provided and may impose reasonable conditions to uphold such confidentiality. For instance, the RIO may stipulate that the recipient sign a confidentiality agreement.

Policy and Procedures for Responding to Allegations of Research Misconduct



C. Decision by Deciding Official

The Research Integrity Officer (RIO) will collaborate with the investigation committee to finalize the draft investigation report, ensuring the incorporation and consideration of comments from the respondent, and subsequently transmit the completed investigation report to the Deciding Official (DO). The DO will then issue a written determination regarding: (1) the acceptance of the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional measures in response to the acknowledged findings of research misconduct. Should the DO's determination deviate from the findings of the investigation committee, the DO will provide a detailed explanation within the written decision.

Alternatively, the DO may return the report to the investigation committee, requesting additional fact-finding or analysis.

Upon reaching a final decision on the case, the RIO typically notifies both the respondent and the complainant in writing. Subsequently, after informing the Office of Research Integrity (ORI), the DO will assess whether law enforcement agencies, professional societies, professional licensing boards, journal editors where falsified reports may have been published, collaborators of the respondent, or other relevant parties should be apprised of the case outcome. The RIO is responsible for ensuring compliance with all notification requirements stipulated by funding or sponsoring agencies.

D. Appeals

Within 15 days of receiving the final report from the Investigation Committee indicating a finding of Research Misconduct, the Respondent may submit a written appeal to the Research Integrity Officer (RIO). This appeal must clearly outline which findings of Research Misconduct are being contested and provide supporting facts and analysis for the Appeals Committee's consideration.

Upon receiving the appeal, the RIO will share it with the relevant parties and/or committee.

Policy and Procedures for Responding to Allegations of Research Misconduct



The Provost will appoint an Appeals Committee comprising three individuals with expertise relevant to the appeal but no prior involvement with the case. The Appeals Committee will follow specific guidelines:

1. Decisions will be made by majority vote.
2. If the Respondent alleges unfair investigation procedures, the committee will assess whether the procedures were consistent with policy and whether any claimed defects prejudiced the Respondent's ability to respond to allegations.
3. If the Respondent disputes the evidence supporting the finding of Research Misconduct, the Appeals Committee must uphold the finding if the Investigation Report presents a reasonable basis for the decision. The Committee cannot reevaluate evidence or consider information outside the investigation record.
4. If new evidence is presented that was unavailable during the initial investigation and is deemed material by the Appeals Committee, the Investigation Committee will reevaluate the evidence and may amend its findings accordingly.

The Appeals Committee will notify the Provost of its decision within 30 days of its formation or 30 days after receiving any amendments to the appeal, unless exceptional circumstances warrant an extension.

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the Research Integrity Officer (RIO) must, within the 120-day timeframe for concluding the investigation [Option: or the 120-day period for concluding any appeal], forward the following documents to ORI:

1. A copy of the final investigation report with all accompanying attachments [Option: and any appeal documents];
2. A declaration indicating whether the institution acknowledges the findings of the investigation report [Option: or the outcome of the appeal];
3. An assertion regarding whether the institution has identified misconduct and, if so, the individual responsible for it;
4. An outline of any ongoing or completed administrative measures taken against the respondent.

Policy and Procedures for Responding to Allegations of Research Misconduct



F. Maintenance of Records for ORI Review

The Research Integrity Officer (RIO) is tasked with retaining and furnishing to ORI, upon request, the "records of research misconduct proceedings" as defined by 42 CFR § 93.317. Unless custody has been transferred to the Department of Health and Human Services (HHS), or ORI has explicitly communicated in writing that the records are no longer required, the records of research misconduct proceedings must be securely maintained for a period of 7 years after the conclusion of the proceedings or the completion of any PHS-related proceedings concerning the research misconduct allegation. Furthermore, the RIO bears the responsibility of supplying ORI with any necessary information, documentation, research records, evidence, or clarification requested to facilitate ORI's review of a research misconduct allegation or the institution's handling thereof.

Research records may include, but are not limited to:

- Research proposals and grant applications
- Raw data and processed data
- Laboratory notebooks and laboratory records
- Clinical research records and study documentation
- Progress reports
- Manuscripts, abstracts, and theses
- Records of oral presentations
- Lab meeting notes or reports
- Online research content
- Journal articles or published papers
- Presentations and posters

These materials may be maintained in a variety of formats, including electronic files, databases, laboratory equipment storage systems, or physical documentation.

1. Sequestration of Research Records

When the Research Integrity Officer (RIO) determines that an allegation of research misconduct warrants an **inquiry**, UMES will promptly take all reasonable and practical steps to obtain all research records and other evidence needed to conduct the research misconduct proceeding.

Policy and Procedures for Responding to Allegations of Research Misconduct



These steps include:

- a. Obtaining custody of relevant research records and other evidence
- b. Creating an **inventory of the records and materials collected**
- c. **Sequestering the records and evidence in a secure manner**

Whenever possible, research records will be obtained **before or at the time the respondent is notified of the allegation**. If additional records become known or relevant during the inquiry or investigation, they will also be obtained and secured.

When research records are located on scientific instruments or systems shared by multiple users, the University may obtain **copies of the relevant data or materials**, provided the copies are substantially equivalent in evidentiary value to the original source data.

2) Types of Research Records That May Be Sequestered

During a research misconduct proceeding, UMES may sequester a wide range of research records and related materials, including but not limited to:

- Forensic copies of computer hard drives
- Physical or electronic laboratory equipment
- Laboratory notebooks documenting experimental procedures or sample preparation
- Proprietary source files or instrument-generated data files
- Graphing, statistical analysis, or image-processing software files
- Data stored on shared laboratory instruments or departmental equipment
- Records from core facilities used for experiments or data analysis

The University will ensure that sequestered materials include records sufficient to document the generation of research data, the analysis of those data, and the preparation of resulting research outputs.



3) Raw Data and Supporting Evidence

Raw data are often critical evidence in research misconduct proceedings. Raw data consist of the **primary observations recorded during the conduct of research before they are processed or modified.**

Sequestered evidence may include:

- Spreadsheets or databases used to record experimental results
- Statistical analysis files
- Image files or figure preparation files
- Instrument-generated data files
- Associated metadata documenting file creation, modification, or processing

Whenever possible, electronic files will be preserved in their **original format** to maintain evidentiary value.

4) Laboratory and Clinical Research Records

When alleged research misconduct involves laboratory or clinical research, the sequestered research records should include documentation sufficient to trace the development of data and results throughout the research lifecycle.

Examples of relevant records may include:

- Study protocols and regulatory documentation
- Source data and original research observations
- Case report forms
- Research subject files and related documentation
- Communications with research sponsors or funding agencies
- Data Safety and Monitoring Board reports
- Drug or device accountability logs

Where clinical research records include protected health information or other legally protected data, the University will ensure that sequestration and review of such records comply with applicable privacy laws and regulatory requirements.

Policy and Procedures for Responding to Allegations of Research Misconduct



5) Chain of Custody and Security

UMES will maintain the integrity of sequestered research records by documenting the **chain of custody** for all records and evidence obtained during the research misconduct proceeding.

Documentation will include:

- The identity of individuals responsible for securing the records
- The location where the records are stored
- Any transfers or access to the records during the proceeding

All sequestered research records and evidence will be stored securely and maintained in accordance with federal regulations governing research misconduct proceedings.

6) Retention of Research Records

Consistent with federal requirements, UMES will maintain all sequestered research records and other evidence related to a research misconduct proceeding in a secure manner for **at least seven (7) years** after completion of the institutional proceeding or any related federal proceeding, whichever is later.

Upon request, the University will provide copies of research records or transfer custody of those records to the U.S. Department of Health and Human Services Office of Research Integrity for purposes of oversight review or administrative proceedings.

IX. COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO ORI

In general, all inquiries and investigations will be carried out until completion, with due diligence applied to address all significant matters. The Research Integrity Officer (RIO) is required to inform the Office of Research Integrity (ORI) in advance if there are intentions to close a case during the inquiry, investigation, or appeal phases. This notification should occur when the closure is based on factors such as the respondent admitting guilt, reaching a settlement with the respondent, or for any other rationale, with the exceptions being: (1) closing a case during the inquiry stage due to the determination that an investigation is unwarranted, or (2) a determination of no misconduct during the investigation stage, which must be reported to ORI in accordance with this policy and 42 CFR § 93.315.

Policy and Procedures for Responding to Allegations of Research Misconduct



X. INSTITUTIONAL ADMINISTRATIVE ACTIONS

If the Deciding Official (DO) determines that research misconduct has been validated by the findings, they will determine the appropriate course of action in consultation with the Research Integrity Officer (RIO). The potential administrative measures may comprise:

- Retraction or amendment of all pending or published abstracts and papers resulting from the research where research misconduct was detected.
- Removal of the accountable individual from the specific project, issuance of a letter of reprimand, implementation of special monitoring for future endeavors, probation, suspension, salary reduction, or initiation of procedures leading to potential demotion or termination of employment.
- Reimbursement of funds to the funding agency as deemed necessary; and
- Implementation of other measures suitable for addressing the research misconduct.

XI. OTHER CONSIDERATIONS

A. Termination or Resignation Before Completion of Inquiry or Investigation

The cessation of the respondent's institutional employment, whether through resignation or other means, either before or after an allegation of potential research misconduct has been reported, will not halt or conclude the research misconduct proceedings nor restrict any of the institution's obligations under 42 CFR Part 93.

Should the respondent, without admitting to misconduct, choose to resign from their position subsequent to the institution receiving an allegation of research misconduct, the evaluation of the allegation will proceed, along with any necessary inquiry and investigation based on the outcomes of preceding steps. If the respondent declines to participate in the process following resignation, the Research Integrity Officer (RIO) and any inquiry or investigation committee will make concerted efforts to reach a determination regarding the allegations, noting in the report the respondent's non-cooperation and its impact on the evidence.

B. Restoration of the Respondent's Reputation

Upon a final determination of no research misconduct, including concurrence from the Office of Research Integrity (ORI) where mandated by 42 CFR Part 93, the RIO must, upon the respondent's request, undertake all reasonable and feasible measures to restore the respondent's reputation. Depending on the specific circumstances and the preferences of the respondent, the RIO should contemplate notifying individuals

Policy and Procedures for Responding to Allegations of Research Misconduct



previously informed about or involved in the investigation of the final outcome, publicizing the resolution in any venue where the research misconduct allegation was previously disclosed, and erasing any reference to the research misconduct allegation from the respondent's personnel record. Any institutional actions aimed at restoring the respondent's reputation must receive prior approval from the Deciding Official (DO).

C. Protection of the Complainant, Witnesses, and Committee Members

Throughout the research misconduct proceedings and upon their conclusion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and feasible measures to safeguard the standing and reputation of, or counteract potential or actual retaliation against, any complainant who made good faith allegations of research misconduct and any witnesses and committee members who cooperated in good faith with the research misconduct proceedings. The DO, in consultation with the RIO and the concerned parties - the complainant, witnesses, or committee members, respectively - will determine what actions, if any, are necessary to restore their respective standing or reputations or to address potential or actual retaliation against them. The RIO is responsible for implementing any approved measures.

D. Allegations Not Made in Good Faith

If applicable, the DO will ascertain whether the complainant's allegations of research misconduct were made in good faith, or if a witness or committee member acted in good faith. Should the DO determine a lack of good faith, he/she will consider whether any administrative action is warranted against the individual who acted without good faith.

E. Honest Error in Research Misconduct Proceedings

1. Purpose

This section establishes how the University of Maryland Eastern Shore (UMES) evaluates and documents claims or evidence of honest error in the context of allegations of research misconduct. The procedures described in this section are intended to ensure that institutional determinations are consistent with the requirements of the **Public Health Service Policies on Research Misconduct (42 CFR Part 93)** and applicable guidance issued by the **U.S. Department of Health and Human Services**.

Policy and Procedures for Responding to Allegations of Research Misconduct



2. Definition and Regulatory Context

Under **42 CFR §93.103**, research misconduct is defined as **fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results**. The regulation explicitly states that **research misconduct does not include honest error or differences of opinion**.

Because research conducted under Public Health Service support is frequently complex, errors may occur in the normal course of research activities. UMES recognizes that actions that initially appear to constitute research misconduct may, upon review, result from honest error. When evaluating allegations of research misconduct, the University will therefore assess whether the evidence indicates that questioned conduct resulted from honest error rather than fabrication, falsification, or plagiarism.

3. Consideration of Honest Error

UMES is not required to disprove the possibility of honest error when no evidence supporting such a claim exists or is presented by the respondent. However, when evidence suggesting honest error is identified—whether introduced by the respondent or identified during institutional review—the University must consider that evidence when determining whether the conduct meets the regulatory definition of research misconduct.

If evidence of honest error is identified during the **inquiry phase**, the Research Integrity Officer (RIO) will ensure that such evidence is documented in the inquiry report in accordance with **42 CFR §93.307(g)(2)**.

UMES will document in inquiry and investigation reports how evidence of honest error was evaluated, including sufficient detail to permit review of the University's reasoning and conclusions by relevant oversight authorities.

If the University determines at either the inquiry or investigation stage that the respondent's actions were the result of honest error and therefore do not meet the definition of research misconduct under **42 CFR Part 93**, the University may close the research misconduct proceeding in accordance with applicable federal requirements.

Policy and Procedures for Responding to Allegations of Research Misconduct



4. Evaluation of Evidence

When considering whether alleged conduct may constitute honest error, UMES will evaluate the credibility, relevance, and context of the available evidence. The University may also consider the scope of the potential misconduct in determining whether the circumstances support a conclusion of honest error.

The University may apply the following evaluative practices:

a. Review of the Research Record

The University will review the respondent's research record to determine whether the practices used are consistent with accepted practices within the relevant research community. The research record may include, but is not limited to:

- Grant proposals and funding applications
- Raw and processed data
- Clinical research documentation

- Laboratory records and laboratory notebooks
- Study records and experimental documentation
- Progress reports
- Manuscripts, abstracts, and theses
- Records of oral or conference presentations
- Online research content
- Laboratory meeting reports
- Published journal articles

b. Assessment of Supporting Evidence

The research record will be examined to determine whether the respondent's explanation that the questioned conduct resulted from an honest error is supported by the available evidence.

Policy and Procedures for Responding to Allegations of Research Misconduct



c. Evaluation of Scope and Pattern

UMES may evaluate whether the alleged issue represents an isolated incident or part of a broader pattern. This may include a limited scoping analysis of related research materials, including grant applications and publications, to identify potential additional concerns.

d. Scientific Plausibility

The inquiry or investigation committee may examine the specific experiments, analyses, or reported results at issue to determine whether the alleged error is scientifically plausible. This assessment may include evaluating whether data appear to have been altered or whether errors consistently change data in ways that support a particular hypothesis.

e. Context of the Respondent's Conduct

The University may consider the respondent's conduct and explanations in context, including whether:

- The respondent acknowledges the mistake when responding to the allegation but provides limited explanation of how the error occurred;
- The respondent demonstrates limited understanding of the relevant scientific methods or procedures such that the error could reasonably occur under the circumstances; or
- The respondent took reasonable steps to correct inaccurate data or otherwise ensure the accuracy and integrity of the research record.

5. Documentation

UMES will maintain documentation of its evaluation of evidence of honest error in inquiry and investigation records. Documentation will include sufficient detail to demonstrate how the evidence was considered and how the University reached its determination regarding whether the actions in question constituted research misconduct.

Policy and Procedures for Responding to Allegations of Research Misconduct



F. Respondent Admissions and Settlement in Research Misconduct Proceedings

1. Purpose

This section establishes the procedures the University of Maryland Eastern Shore (UMES) will follow when a respondent admits to committing research misconduct or when the University reaches a settlement with a respondent during a research misconduct proceeding. These procedures ensure that institutional actions comply with the requirements of the **Public Health Service Policies on Research Misconduct (42 CFR Part 93)** issued by the **U.S. Department of Health and Human Services**.

Federal regulations require institutions receiving Public Health Service (PHS) support to notify the **Office of Research Integrity (ORI)** in advance if the institution intends to close a research misconduct proceeding during the **assessment, inquiry, investigation, or appeal stage** on the basis that the respondent has admitted to committing research misconduct or that a settlement with the respondent has been reached.

Such notification must include both the respondent's written admission statement and the University's written explanation demonstrating that the scope of the misconduct has been fully addressed.

2. Respondent Admission Statement

When a respondent admits to committing research misconduct, the respondent must provide a **written and signed admission statement**. The admission statement must contain the elements required for a research misconduct finding under **42 CFR § 93.103**.

For each allegation of research misconduct admitted, the statement must include the following elements:

a. Type of Research Misconduct

A description of the specific type of research misconduct committed, including fabrication, falsification, plagiarism, or a combination of these actions.

Policy and Procedures for Responding to Allegations of Research Misconduct



b. Affected Research Records

Identification of the research records affected by the misconduct. Examples may include published papers, manuscripts, grant applications, progress reports, presentations, posters, or other research records containing the falsified, fabricated, or plagiarized material or compromised data.

c. Level of Intent

A statement explaining whether the misconduct was committed intentionally, knowingly, or recklessly.

d. Departure from Accepted Practices

An acknowledgement that the respondent's actions represented a significant departure from accepted practices within the relevant research community.

To provide additional clarity regarding the nature of the misconduct, the admission statement should also describe **how the misconduct occurred**, when applicable. This description may include actions such as:

- Image relabeling or reuse
- Data omission or manipulation
- Fabrication of results or data points
- Alteration of images through splicing, rotation, cropping, or other modifications
- Other practices that resulted in falsified or fabricated research findings

The University may provide guidance to assist the respondent in preparing the admission statement, including outlining the required elements described above. However, the statement should be written by the respondent and signed by the respondent to acknowledge responsibility for the misconduct.

Because the admission statement constitutes an acknowledgement of research misconduct, the statement should **not attribute the conduct to honest error, differences of opinion, or mitigating factors**, such as lack of training, equipment malfunction, or misunderstanding of research methods. Assertions of honest error or differences of opinion may instead be raised during the inquiry or investigation process in response to draft reports.

Policy and Procedures for Responding to Allegations of Research Misconduct



3. Institutional Statement Regarding the Admission

The respondent's written admission must be accompanied by a **written statement prepared by UMES** describing how the University determined that the respondent's admission adequately addresses the full scope of the misconduct.

The institutional statement must:

- Explain how the University determined that the **scope of the misconduct is fully addressed by the respondent's admission**;
- Describe the basis for concluding that the **respondent is responsible for the misconduct**; and
- Reference the **institutional record and evidence supporting these conclusions**.

The institutional record should establish the relevant facts of the case, including:

- The identity of the individual responsible for the misconduct;
- The type and extent of the research misconduct;
- How the misconduct occurred;
- The respondent's level of intent; and
- The specific research records affected.

4. Continuation of Proceedings

UMES will ordinarily **carry research misconduct proceedings through completion** and will diligently pursue all significant issues and credible allegations of research misconduct. An early admission by a respondent will not automatically limit the scope of an inquiry or investigation.

The Research Integrity Officer (RIO) and other responsible institutional officials will carefully examine the scope of the allegations and may consult with the **Office of Research Integrity** before determining that a respondent's admission is sufficient to close a proceeding.

In some cases, a respondent may admit to only a portion of the allegations under review. When partial admissions or other complications arise, the University may consult with ORI for technical assistance before determining whether the admission adequately resolves the matter.

Policy and Procedures for Responding to Allegations of Research Misconduct



5. Notification to ORI

If UMES intends to close a research misconduct proceeding at any stage based on a respondent's admission or a settlement agreement, the Research Integrity Officer (RIO) must notify the **Office of Research Integrity in advance**.

The notification must include:

- The respondent's written, signed admission statement; and
- The University's written statement explaining how the scope of the misconduct was fully addressed and how the respondent's culpability was confirmed.

Upon receiving notification, ORI may:

- Consult with the University regarding the proposed closure of the case;
- Conduct an oversight review of the institution's handling of the matter;
- Approve or conditionally approve the closure of the proceeding;
- Direct the University to continue the inquiry or investigation; or
- Require the University to address deficiencies in the institutional record.

UMES will cooperate fully with any oversight review conducted by ORI and will with any directives issued in accordance with **42 CFR Part 93**.

G. Research Misconduct Allegations Involving Multiple Institutions

Research misconduct allegations may involve research conducted collaboratively across multiple institutions. In such cases, **UMES** will address allegations in accordance with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93).

1. Joint Research Misconduct Proceedings

When allegations involve more than one institution, UMES may elect to conduct a joint research misconduct proceeding with the participating institution(s). If a joint proceeding is conducted, one institution must be designated as the lead institution, consistent with federal regulations.

Prior to initiating a joint proceeding, the participating institutions should establish a written agreement, such as a **Memorandum of Understanding (MOU)**, that outlines how the proceeding will be conducted in compliance with applicable regulations and institutional policies.

Policy and Procedures for Responding to Allegations of Research Misconduct



The agreement may address matters including:

- a. The designation of the **lead institution**
- b. The roles and responsibilities of each participating institution
- c. Procedures for obtaining, securing, and sharing relevant research records and other evidence
- d. Institutional points of contact and communication procedures
- e. Protection of confidentiality consistent with federal requirements
- f. The composition of inquiry or investigation committees
- g. Procedures for conducting interviews and committee meetings
- h. How determinations regarding inquiry, investigation, and findings of research misconduct will be made
- i. How institutional actions will be determined
- j. Procedures for resolving disagreements between institutions

The lead institution will generally coordinate the research misconduct proceeding, including the collection of relevant research records and evidence and the conduct of the inquiry or investigation.

2. Designation of the Lead Institution

Participating institutions may determine the lead institution based on factors such as:

- The institution where the respondent is currently employed;
- The institution where the majority of the relevant research records are located; or
- The institution with primary oversight responsibility for the research involved in the allegations.

Institutions may consult with the **U.S. Department of Health and Human Services Office of Research Integrity** for guidance when determining how to coordinate proceedings involving multiple institutions.

3. Independent Institutional Proceedings

In some circumstances, an institution may determine that it will conduct its own research misconduct proceeding rather than participate in a joint process. When conducting an independent proceeding, **UMES** will limit its review and determinations to allegations involving research conducted under its oversight and supported by applicable federal funding.

Policy and Procedures for Responding to Allegations of Research Misconduct



The Research Integrity Officer (RIO) will ensure that inquiry or investigation committees focus their review on allegations within the jurisdiction of the University.

4. Cooperation with Other Institutions

When research misconduct allegations involve multiple institutions, **UMES** will cooperate with other institutions as appropriate to ensure a fair, thorough, and timely review of the allegations, consistent with applicable regulations and confidentiality requirements.

XII. RESEARCH INTEGRITY ASSURANCE AND SUBAWARD COMPLIANCE

A. Research Integrity Assurance

The University of Maryland Eastern Shore (UMES) complies with the requirements of the Public Health Service Policies on Research Misconduct (42 CFR Part 93), issued by the U.S. Department of Health and Human Services, which require institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research to establish and maintain an active research integrity assurance with the Office of Research Integrity (ORI).

An active research integrity assurance confirms that the University:

1. Maintains written policies and procedures for addressing allegations of research misconduct that comply with **42 CFR Part 93**;
2. Adheres to and implements those policies and procedures when responding to allegations of research misconduct; and
3. Complies with all applicable provisions of federal regulations governing research misconduct proceedings.

The Institutional Certifying Official designated by UMES is responsible for providing this assurance to ORI on behalf of the University.

Policy and Procedures for Responding to Allegations of Research Misconduct



B. Maintenance of an Active Assurance

UMES will maintain an active research integrity assurance by complying with all regulatory requirements and by submitting required reports to the Office of Research Integrity.

To maintain compliance, the University will:

1. Ensure that its research misconduct policies and procedures remain consistent with federal regulations;
2. Implement and follow those policies when responding to allegations of research misconduct;
3. Promote a research environment that fosters research integrity and responsible conduct of research;
4. Make its research misconduct policies publicly available to the University community; and
5. Provide additional information regarding research misconduct proceedings to ORI upon request.

The Institutional Certifying Official is responsible for certifying the accuracy and completeness of information submitted to ORI.

C. Annual Reporting Requirements

UMES will submit an annual report on possible research misconduct to the Office of Research Integrity through the ORI Annual Report System.

The annual report will be submitted between **January 1 and April 30** each year and will include information required by ORI concerning the University's compliance with federal research misconduct regulations.

The Institutional Certifying Official will certify the content of the annual report prior to submission.

D. Applicability to Subawardees

Federal regulations require that all recipients of PHS support, including institutions receiving funding through subawards, maintain an active research integrity assurance with ORI.

A subawardee is an institution that receives PHS-supported research funding through a primary awardee or pass-through entity. Subawards may be established through formal agreements, including subcontracts or other legal arrangements associated with federally funded research projects.

Policy and Procedures for Responding to Allegations of Research Misconduct



UMES will ensure that subrecipient institutions participating in PHS-supported research activities maintain compliance with applicable federal research misconduct regulations. When appropriate, UMES may request confirmation that collaborating institutions have established and maintain an active research integrity assurance with ORI.

E. Establishment of a Research Integrity Assurance by Subawardee

Institutions receiving PHS funding through a subaward must establish a research integrity assurance with the **Office of Research Integrity**. This assurance is established when the institution's designated Institutional Certifying Official submits the required assurance documentation to ORI.

To establish an assurance, an institution must:

- a. Provide general institutional information regarding PHS-supported activities;
- b. Identify the institutional officials responsible for addressing research misconduct matters;
- c. Certify that the institution maintains policies and procedures for addressing research misconduct that comply with **42 CFR Part 93**; and
- d. Submit a copy of its research misconduct policies and procedures to ORI, unless the institution qualifies as a small institution as defined by ORI guidance.

F. Small Institution Considerations

In limited circumstances, an institution may qualify as a **small institution** if it lacks the capacity to conduct research misconduct proceedings without an actual or apparent conflict of interest.

Institutions seeking recognition as a small institution may request approval from the Office of Research Integrity to **submit a Small Institution Statement** in lieu of developing full written research misconduct procedures. Such determinations are made in accordance with ORI guidance.

G. Institutional Cooperation with Federal Oversight

UMES will cooperate with the Office of Research Integrity and other components of the U.S. Department of Health and Human Services in matters relating to research misconduct proceedings and institutional compliance with federal regulations.

This cooperation may include providing documentation, responding to requests for additional information, and implementing any administrative actions issued by federal authorities.

Policy and Procedures for Responding to Allegations of Research Misconduct



XIII. COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO ORI

In general, all inquiries and investigations will be carried out until completion, with due diligence applied to address all significant matters. The Research Integrity Officer (RIO) is required to inform the **Office of Research Integrity (ORI)** in advance if there are intentions to close a case during the assessment, inquiry, investigation, or appeal phases on the basis that the respondent has admitted to committing research misconduct, a settlement with the respondent has been reached, or for any other rationale requiring prior notification under federal regulations.

When a research misconduct proceeding may be closed on the basis of a respondent's admission or a settlement agreement, the University of Maryland Eastern Shore will follow the procedures described in **Section XI.F (Respondent Admissions and Settlement in Research Misconduct Proceedings)**, including the requirement to provide ORI with the respondent's written admission statement and the University's written explanation describing how the scope of the misconduct was fully addressed.

Except for closures resulting from a determination during the inquiry stage that an investigation is not warranted, or a determination following investigation that no research misconduct occurred, the RIO will notify ORI in advance of any proposed early closure and will cooperate with any oversight review conducted by ORI in accordance with **42 CFR Part 93**.

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.234 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

§ 93.236 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

Policy and Procedures for Responding to Allegations of Research Misconduct



§ 93.307 Institutional inquiry.

(a) Criteria warranting an inquiry. An inquiry is warranted if the allegation meets the following three criteria:

- (1) Falls within the definition of research misconduct under this part;
- (2) Is within the applicability criteria of § 93.102; and
- (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b) Purpose. An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of the evidence related to the allegation.

(c) Notice to the respondent. At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. Only allegations specific to a particular respondent are to be included in the notification to that respondent. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

(d) Sequestration of records. An institution must obtain all research records and other evidence needed to conduct the research misconduct proceeding, consistent with § 93.305(a).

(e) Conducting the inquiry

(1) Multiple institutions. A joint research misconduct proceeding must be conducted consistent with § 93.305(e).

(2) Person conducting the inquiry. Institutions may convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted. The inquiry review may be done by a RIO or another designated institutional official in lieu of a committee, with the caveat that if needed, these individuals may utilize one or more subject matter experts to assist them in the inquiry.

(3) Interviews. Institutions may interview witnesses or respondents that would provide additional information for the institution's review.

Policy and Procedures for Responding to Allegations of Research Misconduct



(f) Inquiry results.

(1) Criteria warranting an investigation. An investigation is warranted if:

- (i) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and
- (ii) Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.

(2) Findings of research misconduct. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the inquiry stage.

(g) Inquiry report.

(1) The institution must prepare a written report that meets the requirements of this section and § 93.309.

(2) If there is potential evidence of honest error or difference of opinion, the institution must note this in the inquiry report.

(3) The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.

(h) Time for completion.

(1) The institution must complete the inquiry within 90 days of its initiation unless circumstances warrant a longer period.

(2) If the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period.

Policy and Procedures for Responding to Allegations of Research Misconduct



APPENDIX A

RESEARCH INTEGRITY OFFICER RESPONSIBILITIES

I. General Responsibilities

The Research Integrity Officer (RIO) is primarily responsible for ensuring that the institution:

- Takes reasonable steps to cultivate a research environment that upholds responsible conduct, discourages research misconduct, and promptly addresses any allegations or evidence of potential research misconduct.
- Establishes written policies and procedures for addressing research misconduct allegations and reports pertinent information to ORI in accordance with 42 CFR Part 93.
- Abides by its established policies, procedures, and the mandates outlined in 42 CFR Part 93.
- Educates its members subject to 42 CFR Part 93 about the institution's research misconduct policies, procedures, and its commitment to adherence.
- Implements suitable interim measures during research misconduct proceedings to safeguard public health, federal funds, equipment, and the integrity of PHS-supported research activities.

II. Notice, Reporting, and Collaboration with ORI

The RIO's main duties involve ensuring that the institution:

- Submits an annual report to ORI containing the specified information.
- Furnishes ORI, along with the annual report, any additional aggregated information concerning the institution's research misconduct proceedings and compliance with 42 CFR Part 93, as directed by ORI.
- Promptly alerts ORI if, during the research misconduct process, it perceives risks to public health, safety, HHS resources, violations of law, or the need for federal intervention, public disclosure, or suspension of research activities.
- Furnishes ORI with the official determination to initiate an investigation and a copy of the inquiry report within 30 days of this determination.

Policy and Procedures for Responding to Allegations of Research Misconduct



- Notifies ORI promptly when commencing an investigation.
- Provides ORI, within 120 days of commencing an investigation (or as extended by ORI), with the investigation report, the institution's stance on the investigation findings, any identified research misconduct, the responsible party, and details of any administrative actions taken against the respondent.
- Seeks ORI's prior approval if considering closing a case at any stage before completion based on specific grounds, except in certain circumstances explicitly outlined.
- Extensively collaborates with ORI during oversight reviews, administrative hearings, or appeals, by supplying all relevant research records, evidence, and access to pertinent individuals under its jurisdiction.

III. Research Misconduct Proceedings

A. General Oversight

The RIO's overarching responsibilities encompass:

- Promptly securing all pertinent research records and evidence required for conducting the research misconduct proceedings, ensuring their proper inventory, and safeguarding them securely.
- Ensuring the cooperation of respondents and other institutional members during the research misconduct proceedings.
- Upholding confidentiality standards as per 42 CFR § 93.108 and institutional policy.
- Assessing potential conflicts of interest among individuals involved in handling research misconduct allegations and taking necessary actions, including recusal, to maintain impartiality.
- Providing regular updates to the Deciding Official (DO) and other pertinent stakeholders regarding the progress of the research misconduct review.
- Collaborating with relevant institutional officials to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members, and mitigate any retaliation they may face.
- Endeavoring, upon request and where appropriate, to safeguard or reinstate the reputation of individuals accused of research misconduct but not found guilty.
- Assisting the DO in implementing administrative actions against individuals found not to have acted in good faith.
- Maintaining detailed records of the research misconduct proceedings securely for seven years following their conclusion.

Policy and Procedures for Responding to Allegations of Research Misconduct



B. Allegation Receipt and Assessment

In this capacity, the RIO is responsible for:

- Providing confidential consultations to individuals uncertain about reporting research misconduct.
- Receiving and evaluating allegations of research misconduct to determine if an inquiry is warranted based on specific criteria.

C. Inquiry Proceedings

The RIO is tasked with:

- Initiating the inquiry process when deemed appropriate.
- Ensuring timely notification of the respondent, if known, at the outset of the inquiry.
- Securing necessary research records and evidence before commencing the inquiry.
- Appointing an inquiry committee and outlining its charge and responsibilities.
- Facilitating the inquiry committee's operations, including organizing meetings, providing logistical support, and guiding the committee in preparing the inquiry report.
- Reviewing and transmitting the final inquiry report to the DO for a determination on whether an investigation is warranted.
- Promptly notifying ORI of the decision to proceed with an investigation.

D. Investigation Proceedings

In this capacity, the RIO's responsibilities include:

- Initiating the investigation within 30 calendar days following a DO decision to proceed.
- Notifying ORI and the respondent of the investigation commencement and the allegations being investigated.
- Acquiring and sequestering additional research records and evidence before formally notifying the respondent.
- Appointing an investigation committee and delineating its charge.
- Facilitating the investigation committee's activities and providing necessary support.
- Overseeing the investigation's progress and ensuring adherence to established procedures and standards.
- Requesting an extension from ORI if the investigation cannot be completed within the prescribed timeframe.

Policy and Procedures for Responding to Allegations of Research Misconduct



- Assisting the investigation committee in drafting the investigation report, soliciting feedback from the respondent, and ensuring confidentiality.
- Transmitting the draft and final investigation reports to the DO and subsequently to ORI along with relevant documentation and administrative actions taken.
- Notifying the respondent and complainant of the final decision and coordinating notifications to other relevant parties.
- Maintaining and providing ORI with all pertinent research records and documentation upon request.