



PROCEDURE FOR INSTITUTIONAL POLICY R-03: RESEARCH MISCONDUCT

1. PURPOSE

The West Virginia School of Osteopathic Medicine ("WVSOM") bears primary responsibility for prevention and detection of research misconduct associated with the institution. The purpose of this procedure is to promote integrity in research and to ensure that WVSOM complies with state and federal laws, rules, and regulations regarding research misconduct.

2. APPLICABILITY

2.1 This procedure applies to institutional members and all research misconduct involving research, research training, and related research activities, including the application for research funding whether or not funds are awarded, occurring within six (6) years of the date WVSOM receives an Allegation of Research Misconduct, subject to the following exceptions:

2.1.1 The six-year time limitation does not apply if the Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six-year period through the use of, replication of, or citation to the portion(s) of the Research Record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the Respondent ("Subsequent Use Exception"). For alleged Research Misconduct that appears subject to this Subsequent Use Exception, but WVSOM determines is not subject to the exception, WVSOM will document its determination that the Subsequent Use Exception does not apply and will retain this documentation for the later of seven (7) years after the completion of the Research Misconduct Proceeding or the completion of any HHS proceeding.

2.1.2 The six-year time limitation also does not apply if the Office of Research Integrity ("ORI") or WVSOM, following consultation with ORI, determines that the alleged Research Misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

2.2 WVSOM reserves the right to amend this procedure at any time, as necessary or appropriate.

3. DEFINITIONS

For purposes of this procedure, the capitalized terms used herein have the meanings assigned to them in Institutional Policy R-03: Research Misconduct.

4. REPORTING ALLEGATIONS OF RESEARCH MISCONDUCT

All Institutional Members must report observed, suspected, or apparent Research Misconduct to the Research Integrity Officer. If the circumstances described by the individual do not meet the definition of Research Misconduct, the Research Integrity Officer will refer the individual to other offices or officials with responsibility over the reported matter.

5. CONDUCTING THE ASSESSMENT

5.1 Upon receiving an Allegation of Research Misconduct, the Research Integrity Officer will immediately assess the Allegation to determine whether the Allegation falls within the definition of Research Misconduct and whether it is sufficiently credible and specific so that potential Evidence may be identified. An Inquiry must be conducted if these criteria are met.

- 5.2 The Assessment period should be brief, preferably concluded within a week. In conducting the Assessment, the Research Integrity Officer need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the Allegation, and only involves the review of readily accessible information relevant to the Allegation.

6. CONDUCTING THE INQUIRY

6.1 Initiation of the Inquiry

- 6.1.1 If the Research Integrity Officer determines that the criteria for an Inquiry are met, he or she will immediately initiate the Inquiry process. The purpose of the Inquiry is to conduct an initial review of the available Evidence to determine whether to conduct an Investigation. An Inquiry does not require a full review of all the Evidence related to the Allegation.
- 6.1.2 On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the Research Integrity Officer must take all reasonable and practical steps to obtain custody of all the Research Records and other Evidence, which may include copies of data or other Evidence so long as those copies are substantially equivalent in evidentiary value, needed to conduct the Research Misconduct Proceeding, inventory the records and Evidence and sequester them in a secure manner. Where the Research Records or other Evidence are located on or encompass scientific instruments shared by multiple users, WVSOM may obtain copies of the data or other Evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments. WVSOM has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the Inquiry or Investigation.
- 6.1.3 At the time of or before beginning an Inquiry, the Research Integrity Officer must make a Good Faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, the Research Integrity Officer must notify them in writing.

6.2 Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with the Vice President of Academic Affairs and Dean, will appoint an Inquiry committee and committee chair as soon after the initiation of the Inquiry as is practical. The Inquiry committee must consist of at least three (3) individuals (must be an odd number) who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the Evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Inquiry.

6.3 Instructions to the Inquiry Committee

- 6.3.1 The Research Integrity Officer will prepare a charge sheet for the Inquiry committee that:
- a. Defines Research Misconduct;
 - b. Describes the Allegations and any related issues identified during the Assessment;
 - c. Informs that the scope and purpose of the Inquiry is to conduct an initial review of the Evidence and determine whether an Investigation is warranted. The scope does not include deciding whether Research Misconduct definitely occurred, determining definitely who committed the Research Misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of Research Misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case and if required by law, WVSOM shall promptly consult with the

applicable federal agency to determine the next steps that should be taken. (See Section 8 below.)

- d. Provides the criteria required for determining that an Investigation is warranted: (1) there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct and involves Research, Research training or related activities; and, (2) the Allegation may have substance, based on the committee's review during the Inquiry; and
- e. Sets forth the deadlines required by Sections 6.4, 6.5, and 6.6 for completion of the Inquiry.

6.3.2 At the committee's first meeting, the Research Integrity Officer will review the charge and the prescribed procedures and standards for the conduct of the Inquiry, including the necessity for confidentiality and for developing a specific Inquiry plan. The Investigation committee will be provided with a copy of this procedure.

6.4 Inquiry Committee Responsibilities

- 6.4.1 The Inquiry committee will interview the Complainant, the Respondent, and key witnesses as well as examine relevant Research Records and materials. The Research Integrity Officer will be present or available throughout the Inquiry to advise the committee as needed.
- 6.4.2 The committee will evaluate the Evidence and make a recommendation on whether an Investigation is warranted based on the criteria in Section 6.3.1.c above.
- 6.4.3 The committee chair will prepare a written report of the Inquiry that includes the name and position of the Respondent, a description of the Allegations of Research Misconduct, any federal agency support, and the basis for recommending or not recommending that the Allegations warrant an Investigation.
- 6.4.4 The committee will deliver the draft report to the Research Integrity Officer.

6.5 Final Decision and Inquiry Report

- 6.5.1 The Research Integrity Officer will transmit the Evidence and draft Inquiry report to the Vice President of Academic Affairs and Dean ("VP of Academic Affairs"). The VP of Academic Affairs must evaluate the Evidence and decide whether an Investigation is warranted based on the criteria in Section 6.3.1.c above.
 - a. If an Investigation is warranted, the Respondent will be removed as signatory for any grants on which he or she is principal investigator. As the Respondent may remain eligible to all faculty rights of salary, rank, and title while the Investigation is carried forward, WVSOM must utilize sources other than grant funds if a portion of the Respondent's salary was designated to be paid by the sponsoring agency.
 - b. If an Investigation is not warranted, the Research Integrity Officer shall secure and maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by the applicable federal agency of the reasons why an Investigation was not conducted. These documents must be provided to the federal agency upon request.
- 6.5.2 The VP of Academic Affairs shall notify the Respondent whether the Inquiry found an Investigation to be warranted. The Notice to the Respondent must include a copy of the draft Inquiry report, a copy of or reference to 42 C.F.R. Part 93 if PHS funds were applied for or used, and a copy of WVSOM's policies and procedures on Research Misconduct. The Respondent will be allowed five (5) business days from the date he/she received the draft Inquiry report to submit comments to the VP of Academic Affairs.

- 6.5.3 Based on the comments, the VP of Academic Affairs may revise the draft report as appropriate. The VP of Academic Affairs will prepare the final Inquiry report, which must include the following information:
- a. The name and position of the Respondent;
 - b. A description of the Allegations of Research Misconduct;
 - c. Any federal support, including, for example, grant numbers, grant applications, contracts and publications listing the support;
 - d. The composition of the Inquiry committee, if used, including name(s), position(s), and subject matter expertise;
 - e. An inventory of sequestered Research Records and other evidence and a description of how sequestration was conducted;
 - f. Transcripts of interviews, if transcribed;
 - g. Inquiry timeline and procedural history;
 - h. Any scientific or forensic analysis conducted;
 - i. The basis for recommending or not recommending that the Allegations warrant an Investigation;
 - j. Any comments on the draft report submitted by the Respondent(s) or the Complainant(s);
 - k. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies; and
 - l. Documentation of potential Evidence of honest error of difference of opinion.
- 6.5.4 The VP of Academic Affairs will deliver the final Inquiry report to the Research Integrity Officer.

6.6 Time for Completion

The Inquiry, including preparation of the final Inquiry report and the decision of the VP of Academic Affairs on whether an Investigation is warranted, must be completed within 90 calendar days of initiation of the Inquiry, unless the Research Integrity Officer determines that circumstances clearly warrant a longer period. If the Research Integrity Officer approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 90-day period. The Respondent will be notified of the extension.

7. EVIDENTIARY STANDARDS FOR FINDINGS

7.1 Standard of Proof

A WVSOM finding of Research Misconduct must be proved by a Preponderance of the Evidence.

7.2 Burden of Proof

- 7.2.1 WVSOM has the burden of proof for making a finding of Research Misconduct. The destruction of or the Respondent's refusal to provide Research Records adequately documenting the questioned Research is Evidence of Research Misconduct where WVSOM establishes by a Preponderance of the Evidence that the Respondent Intentionally, Knowingly, or Recklessly had Research Records and destroyed or maintained the records

and refused to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

7.2.2 The Respondent has the burden of going forward with and the burden of proving, by a Preponderance of the Evidence, any and all affirmative defenses raised. In determining whether WVSOM has carried the burden of proof imposed by this procedure, the finder of fact shall give due consideration to admissible, credible Evidence of honest error or difference of opinion presented by the Respondent.

7.2.3 The Respondent has the burden of going forward with and proving by a Preponderance of the Evidence any mitigating factors that are relevant to a decision to impose administrative actions following a Research Misconduct Proceeding.

8. CONDUCTING THE INVESTIGATION

8.1 Custody of Research Records and Evidence

The Research Integrity Officer must, prior to notifying Respondent of the Allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all Research Records and Evidence needed to conduct the Research Misconduct Proceeding that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including WVSOM's decision to investigate additional Allegations not considered during the Inquiry stage or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

8.2 Notification of Investigation

8.2.1 The Research Integrity Officer must provide a copy of the final inquiry report, including the Allegations to be investigated, to the Respondent within a reasonable time after determining that an Investigation is warranted, but before the Investigation begins. The Research Integrity Officer must also give the Respondent written Notice of any new Allegations of Research Misconduct within a reasonable amount of time of deciding to pursue Allegations not addressed during the Inquiry or in the initial Notice of the Investigation.

8.2.2 If required by law, the Research Integrity Officer must notify the applicable federal agency of the decision to begin the Investigation and provide the federal agency a copy of the Inquiry report. The federal agency must receive the decision and Inquiry report on or before the date on which the Investigation begins but no later than 30 calendar days of finding that an Investigation is warranted. The Research Integrity Officer must provide the following information to the federal agency upon request: (1) the institutional policies and procedures under which the Inquiry was conducted; (2) the Research Records and Evidence reviewed, transcripts of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.

8.3 Initiation of the Investigation

The Investigation must begin within 30 calendar days after the determination by the VP of Academic Affairs that an Investigation is warranted. The purpose of the Investigation is to develop a factual record by exploring the Allegations in detail and examining the Evidence in depth, leading to recommended findings on whether Research Misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial Allegations. This is particularly important where the alleged Research Misconduct involves potential harm to human subjects or the general public or if it affects Research that forms the basis for public policy, clinical practice, or public health practice.

8.4 Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with the VP of Academic Affairs, will appoint an Investigation committee and the committee chair as soon after the beginning of the Investigation as is practical. The Investigation committee must consist of at least three (3) individuals (must be an odd number) who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation and should include individuals with the appropriate scientific expertise to evaluate the Evidence and issues related to the Allegation, interview the Respondent and Complainant and conduct the Investigation. Individuals appointed to the Investigation committee may also have served on the Inquiry committee.

8.5 Instructions to the Investigation Committee

8.5.1 The Research Integrity Officer will prepare a charge sheet for the Investigation committee that:

- a. Defines Research Misconduct;
- b. Describes the Allegations and related issues identified during the Inquiry;
- c. Informs the committee that it must evaluate the Evidence and testimony to determine whether, based on a Preponderance of the Evidence, Research Misconduct occurred and, if so, the type and extent of it and who was responsible;
- d. Provides the criteria required for determining that the Respondent committed Research Misconduct: (1) there was a significant departure from accepted practices of the relevant Research community; (2) the misconduct was committed Intentionally, Knowingly, or Recklessly; and (3) the Allegation must be proven by a Preponderance of the Evidence;
- e. Provides that the Respondent has the burden of proving by a Preponderance of the Evidence any affirmative defenses raised, including honest error or a difference of opinion; and
- f. Sets forth the deadlines required by Sections 8.6, 8.7, 8.8 and 8.9 for completion of the Investigation.

8.5.2 At the committee's first meeting, the Research Integrity Officer will review the charge, the Inquiry report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation committee will be provided with a copy of this procedure.

8.6 Investigation Committee Responsibilities

8.6.1 The Investigation committee must conduct the Investigation under the following standards:

- a. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all Research Records and Evidence relevant to reaching a decision on the merits of each Allegation;
- b. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
- c. Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and transcribe each interview, provide the transcript to the interviewee for correction, and include the transcript(s) with any corrections in the record of the Investigation, and provide the

Respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality; and

- d. Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any Evidence of any additional instances of possible Research Misconduct, and continue the Investigation to completion.

8.6.2 The committee will evaluate the Evidence and Inquiry report, and make a recommendation based on a Preponderance of the Evidence of whether Research Misconduct occurred based on the criteria in Section 8.5.1.d above. The Research Integrity Officer will be present or available throughout the Investigation to advise the committee as needed.

8.7 Investigation Report

8.7.1 The Investigation committee must prepare a written draft report of the Investigation for each Respondent that:

- a. Describes the nature of the Allegation of Research Misconduct, including any additional Allegation(s) addressed during the Research Misconduct Proceeding;
- b. Describes and documents the applicable federal agency support, if any, including, for example, the grant numbers, grant applications, contracts, publications listing the federal agency support, and includes known applications or proposals for support that the Respondent has pending with federal agencies;
- c. Describes the institutional charge and specific Allegations of Research Misconduct considered in the Investigation;
- d. Includes the composition of the Investigation committee, including name(s), position(s), and subject matter expertise;
- e. Includes WVSOM's policies and procedures under which the Investigation was conducted;
- f. Includes an inventory of sequestered Research Records and other Evidence, except records WVSOM did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the Investigation. The inventory will also include a description of how any sequestration was conducted during the Investigation.
- g. Includes transcripts of all interviews conducted;
- h. Identifies the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other Research Records that contain the allegedly falsified, fabricated, or plagiarized material;
- i. Describes any scientific or forensic analysis conducted;
- j. Includes any comments made by the Respondent and Complainant(s) on the draft Investigation report and the committee's consideration of those comments ; and
- k. Includes a statement of findings for each Allegation of Research Misconduct identified during the Investigation. For each separate Allegation of Research Misconduct, the statement must provide a finding as to whether Research Misconduct did or did not occur, and if so: (1) identify whether the Research Misconduct was Falsification, Fabrication, or Plagiarism, and whether it was committed Intentionally, Knowingly, or in Reckless disregard; (2) summarize the facts and the analysis which support the conclusion and

consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a Preponderance of the Evidence that he or she did not engage in Research Misconduct because of honest error or a difference of opinion; (3) identify the specific federal agency support, if any; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the Respondent has pending with other federal agencies.

- 8.7.2 The Research Integrity Officer must give the Respondent a copy of the draft report of Investigation for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 calendar days from the date he/she received the draft report to submit written comments on the draft report to the Research Integrity Officer. The Research Integrity Officer will immediately provide the written comments received, if any, to the Investigation committee for consideration. The Investigation committee will consider and address the Respondent's written comments before issuing the final report.
- 8.7.3 The Investigation committee will prepare the final report of Investigation and deliver it to the Research Integrity Officer.
- 8.8 Final Decision
 - 8.8.1 The Research Integrity Officer will transmit the final Investigation report to the VP of Academic Affairs. The VP of Academic Affairs will determine in writing:
 - a. Whether WVSOM accepts the Investigation report, its findings, and the recommended institutional actions; and
 - b. The appropriate institutional actions in response to the accepted findings of Research Misconduct. If this determination varies from the findings of the Investigation committee, the VP of Academic Affairs will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation committee. Alternatively, the VP of Academic Affairs may return the report to the Investigation committee with a request for further fact-finding or analysis.
 - 8.8.2 When a final decision has been reached, the VP of Academic Affairs will notify the Respondent and the Research Integrity Officer in writing. Institution decisions regarding Research Misconduct are considered final and are independent of ORI findings.
 - 8.8.3 After informing the applicable federal agency if required by law, the VP of Academic Affairs will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case.
- 8.9 Other Procedures and Special Circumstances
 - 8.9.1 Multiple Respondents: If additional Respondents are identified during an Inquiry or Investigation, WVSOM is not required to conduct a separate Inquiry for each new Respondent. However, each additional Respondent must be provided Notice of and an opportunity to respond to the Allegations, consistent with these procedures.
 - 8.9.2 Multiple Institutions: If the alleged Research Misconduct involves multiple institutions, WVSOM may work closely with the other affected institutions to determine whether a joint Research Misconduct Proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint Research Misconduct Proceeding, the lead institution will obtain Research Records and other Evidence pertinent

to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint Research Misconduct Proceeding may include committee members from the institutions involved. The determination of whether further Inquiry and/or Investigation is warranted, whether Research Misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

8.10 Notice to Federal Agency

Unless an extension has been granted as provided in Section 8.10 below, the Research Integrity Officer must, within the 180-day period for completing the Investigation, submit to the applicable federal agency, if required by law, the following: (1) a copy of the final Investigation report; (2) a copy of the institutional record as defined in 3.10; (3) a statement of whether WVSOM accepts the findings of the Investigation report; (4) a statement of whether WVSOM found Research Misconduct and, if so, who committed the misconduct; and (5) a description of any pending or completed administrative actions against the Respondent.

8.11 Time for Completion

8.11.1 The Investigation must be completed within 180 calendar days of beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report for comment, and, if required by law, sending the final report to the applicable federal agency as required by Section 8.9 above.

8.11.2 If the Research Integrity Officer determines that the Investigation will not be completed within this 180-day period, he/she will submit to the applicable federal agency, if required by law, a written request for an extension, setting forth the reasons for the delay. If the federal agency grants the request for an extension and directs the filing of periodic progress reports, the Research Integrity Officer will ensure that such reports are filed with the federal agency as directed.

8.12 Disciplinary Action

If Research Misconduct was found, the disciplinary process, including the determination of the nature and severity of the disciplinary action, shall follow applicable WVSOM policies and procedures on disciplinary actions. Disciplinary actions available to WVSOM include but are not limited to the following:

- a. Removal from a particular project;
- b. Letter of reprimand;
- c. Special monitoring of future work;
- d. Probation;
- e. Suspension;
- f. Salary reduction;
- g. Rank reduction;
- h. Termination of employment; and/or
- i. Expulsion.

8.13 Maintaining Records

- 8.13.1 If required by law, the Research Integrity Officer must maintain and provide to the applicable federal agency upon request all records of Research Misconduct Proceedings.
- 8.13.2 Unless custody has been transferred to the federal agency or the federal agency has advised in writing that the records no longer need to be retained, records of Research Misconduct Proceedings must be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any federal agency proceeding involving the Research Misconduct Allegation, whichever is later.
- 8.13.3 The Research Integrity Officer must provide any information, documentation, Research Records, Evidence or clarification requested by the federal agency to carry out its review or analysis of an Inquiry or Investigation or of WVSOM's handling of a Research Misconduct Allegation.

9. COMPLETION OF CASES

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. If required by law, the Research Integrity Officer must notify the applicable federal agency in advance if there are plans to close a case at the Inquiry or Investigation stage on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except: (1) closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no misconduct at the Investigation stage, which must be reported to the federal agency, as prescribed in this procedure.

10. GENERAL PROVISIONS

10.1 Cooperation with Research Misconduct Proceedings

Institutional Members, including Respondents, will cooperate with the Research Integrity Officer and other WVSOM officials in the review of Allegations and the conduct of Inquiries and Investigations, and have an obligation to provide Evidence relevant to Research Misconduct Proceedings.

10.2 Confidentiality

10.2.1 Disclosure of the identity of Respondents, Complainants, and witnesses while conducting the Research Misconduct Proceedings is limited, to the extent possible, to those who need to know, as determined by WVSOM, consistent with a thorough, competent, objective and fair Research Misconduct Proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. Provided, however, that:

- a. WVSOM must disclose the identity of Respondents and Complainants to federal agencies pursuant to a federal review of Research Misconduct Proceedings, as required by law.
- b. Certain federal administrative hearings must be open to the public, as required by law.
- c. . This limitation on disclosure of the identity of Respondents, Complainants, and witnesses no longer applies once an institution has made a final determination of Research Misconduct findings.

10.2.2 Except as otherwise prescribed by applicable law, confidentiality must be maintained for any records or Evidence from which Research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a Research Misconduct Proceeding.

- 10.2.3 The Research Integrity Officer should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

10.3 Protecting Informants and Committee Members

- 10.3.1 Institutional Members may not retaliate in any way against Complainants, witnesses, or committee members.
- 10.3.2 Institutional Members should immediately report any alleged or apparent Retaliation to the Research Integrity Officer, who shall review the matter and make all reasonable and practical efforts to counter any potential or actual Retaliation and protect and restore the position and reputation of the person against whom the Retaliation is directed.

10.4 Protecting Respondents

- 10.4.1 As requested and as appropriate, WVSOM shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in Research Misconduct, but against whom no finding of Research Misconduct is made.
- 10.4.2 A Respondent may consult with legal counsel or a non-lawyer advisor (who is not a principal or witness in the case) to seek advice and may bring the counsel or advisor to proceedings involving the Respondent. The Respondent's counsel or advisor may serve in an advisory capacity to the Respondent in such proceedings, but may not speak on behalf of the Respondent or otherwise participate directly in the proceedings. The Respondent is responsible for all costs incurred relating to the use of counsel or an advisor.

10.5 Allegations Not Made in Good Faith

If WVSOM determines that a Complainant's Allegation of Research Misconduct was not made in Good Faith, or whether a witness or committee member did not act in Good Faith, WVSOM may take administrative action against the person who failed to act in Good Faith.

10.6 Respondent's Termination or Resignation

The termination of the Respondent's employment, by resignation or otherwise, before or after an Allegation of possible Research Misconduct has been reported, will not preclude or terminate the Research Misconduct Proceeding or otherwise limit any of WVSOM's responsibilities under this procedure. If the Respondent refuses to participate in the process after resignation, WVSOM will use its best efforts to reach a conclusion concerning the Allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

10.7 Interim Administrative Actions and Notice to federal agency of Special Circumstances

- 10.7.1 If required by federal law, at any time during a Research Misconduct Proceeding, WVSOM shall immediately notify the applicable federal agency if any of the following conditions exist:
- a. The health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
 - b. The agency's resources or interests are threatened;
 - c. Research activities should be suspended;
 - d. There is a reasonable indication of possible violations of civil or criminal law;

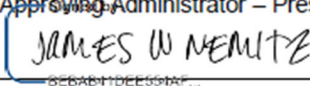
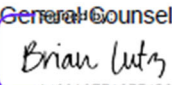
- e. Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;
- f. The Research Misconduct Proceeding may be made public prematurely and federal action may be necessary to safeguard Evidence and protect the rights of those involved; or
- g. The Research community or public should be informed.

10.7.2 WVSOM shall take appropriate interim action to protect against any threat of harm to public health, federal funds and equipment, or the integrity of the Research process. Interim action may include additional monitoring of the Research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication.

10.8 In the event the Research Integrity Officer, the Vice President of Academic Affairs, or any other administrator referenced in this procedure has an unresolved personal, professional, or financial conflict of interest with those involved with the Inquiry or the Investigation or if the Allegation of Research Misconduct is against that administrator, then the WVSOM President shall designate another administrator to assume the duties of the conflicted administrator under this procedure.

11. REFERENCES

- 11.1 Federal Policy on Research Misconduct, National Science and Technology Council, Executive Office of the President of the United States, December 6, 2000.
- 11.2 Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93 (2024).

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