

Policy on Misconduct in Research

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Winthrop University

Policy on Misconduct in Research

I. Statement of Purpose and Applicability

A. Purpose Statement

Winthrop University will provide an open and stimulating environment for creativity and individual thought so that all faculty will have the opportunity to develop independently and productively in their chosen field. This climate is meant to promote high ethical standards and enhance the research process.

Furthermore, students, administrators and staff conducting research will be expected to adhere to ethical standards and will be subject to provisions set forth in this policy.

In recognition of the possibility that improprieties may occur, institutional policies and procedures relating to misconduct in research are hereby adopted

B. Definitions

1. Research: The systematic investigation designed to develop or contribute to generalizable knowledge in all areas of research, including the humanities, arts, education, and physical, behavioral and social-sciences disciplines. Research includes all research conducted using University facilities or under the auspices of the University, whether independently funded by the researcher, funded by Winthrop University and/or by external funding sponsors.
2. Researcher: Throughout this policy, the individual alleged to have committed the misconduct will be referred to as the Researcher.
3. Unit Head: Deans and Vice Presidents of the University
4. Inquiry Committee: Committee of a minimum of three members, appointed by the Academic Vice President, charged with reviewing an allegation to determine if an investigation is warranted. (See Section III – B,C)
5. Investigative Committee: Committee of a minimum of five members, three of whom work outside of the Researcher's department, appointed by the Academic Vice President and charged with the evaluation of the evidence and testimony to determine whether, based on a preponderance of evidence, research misconduct occurred and, if so, the type and extent of the misconduct and who was responsible for the misconduct. (See Section IV – A, C)
6. Institutional Members: Winthrop University faculty, administrators, staff and students

C. Definition of Research Misconduct (42CFR 93.103)

Research misconduct means fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results as defined below:

1. Fabrication is making up data or results and recording or reporting them.
2. 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.
3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
4. Unauthorized use of privileged information, such as information gained via review of proposals and manuscripts, information covered by confidentiality agreements, and other types of confidential research information.

5. Research misconduct does not include honest error or honest differences in interpretations or judgments of data.

A finding of research misconduct requires: (42CFR93.104)

1. A significant departure from accepted practices of the relevant research community; and
2. The misconduct be committed intentionally, knowingly or recklessly; and
3. The allegation be proven by a preponderance of evidence.

D. Application of Policy

This policy will apply to research conducted by faculty, students of the University, or any person, who at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with Winthrop University.

II. General Policies and Principles

A. Responsibility to Report Misconduct

All Winthrop institutional members will report observed, suspected or apparent research misconduct to the Winthrop University Compliance Officer. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, s/he should contact the Compliance Officer to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the Compliance Officer will refer the individual or allegation to other offices or officials with responsibility for solving the problem.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the Compliance Officer, the Inquiry and/or Investigation Committee and other university officials in the review of allegations, the conduct of inquiries and the conduct of investigations. Institutional members shall have an obligation to provide evidence relevant to research misconduct allegations as required by officials conducting the inquiry and investigation.

C. Confidentiality

The disclosure of all parties involved in the investigation, including the individual reporting the misconduct and the individual accused of misconduct will be limited to those who need to know in order to carry out a thorough, competent, objective and fair inquiry and investigation. In addition, the disclosure of records or evidence from which research subjects might be identified will be limited to those conducting the inquiry and investigation that have a need to know. Recipients of confidential information in the course of the inquiry or investigation will be required to sign a written confidentiality agreement to ensure that the recipient does not make any further disclosure of identifying information.

The disclosure of the identity of research subjects will be reported to the Institutional Review Board as an adverse event in accordance with Section 3.6 of the Winthrop University Institutional Review Board Policies and Guidelines.

D. Protecting individuals reporting misconduct, witnesses and committee members

Institutional members may not retaliate in any way against individuals reporting misconduct, witnesses testifying in the inquiry or investigation, and individuals conducting the inquiry or investigation. Any alleged or apparent retaliation shall immediately be reported to the Compliance Officer, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the

retaliation is directed.

E. Protecting the Researcher accused of misconduct

The Compliance Officer and other university officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the inquiry and investigation, the Compliance Officer is responsible for ensuring that individuals alleged to have engaged in research misconduct, receive all notices and opportunities called for in these policies and in any Federal regulations governing the research. Individuals may consult with legal counsel or a non-lawyer personal advisor (who is not a principal or witness in the inquiry or investigation) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the inquiry or investigation.

F. Interim Administrative Actions

Throughout the research misconduct inquiry and investigation, the Compliance Officer will review the situation to determine if there is any threat of harm to public health, project funding and/or equipment or the integrity of the research process. In the event of such a threat, the Compliance Officer will, in consultation with other university officials, take appropriate interim action to protect against any such threat.

If the research is funded by external funding agencies, the Compliance Officer will ensure that the policies and procedures of the external agency are followed in reporting misconduct in research.

III. Conduct of the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the Compliance Officer will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and meets the definition in Part I.C. of this policy.

The Compliance Officer will provide a written assessment report to the Academic Vice President and the Unit Head of the organization unit in which the alleged misconduct occurred. The Compliance Officer, the Academic Vice President and the Unit Head of the organizational unit in which the misconduct occurred will review the assessment findings to determine if the criteria under Part I.C. has been met, and if this criteria is met an inquiry must be conducted.

The assessment period should be brief and conclude within one week of the report of misconduct in research. The Compliance Officer shall, on or before the date the researcher is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct inquiry.

B. Initiation and Purpose of the Inquiry

The Compliance Officer will notify the researcher in writing of the inquiry and take custody of research records and evidence needed to conduct the research misconduct inquiry, inventory the records and evidence, and sequester them in a secure manner.

The Academic Vice President will appoint an inquiry committee and committee chair as soon as practical. The committee must consist of at least three (3) individuals who do not have unresolved

personal, professional or financial conflicts of interest with those involved in the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation.

If the research involved any of the following three compliance areas, a member of the appropriate compliance committee will also sit on the inquiry committee:

- Research with human subjects – Institutional Review Board
- Research with vertebrates – Institutional Animal Care and Use Committee
- Research with Bio-hazardous materials – BioSafety Committee

C. Charge to the Inquiry Committee and First Meeting

The Compliance Officer will prepare a charge for the inquiry committee that:

- Advises the committee that the inquiry must be completed within 60 calendar days of initiation of the inquiry and that a written report of the inquiry is to be given to the Academic Vice President, Unit Head, Compliance Officer and Researcher at the conclusion of the inquiry.
- Advises the committee that all proceedings are confidential and limited to a “need to know” basis
- Describes the allegations and any related issues identified during the allegation assessment
- States that the purpose of the inquiry is to conduct an initial review of the evidence, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible.
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, and (2) the allegation may have substance, based on the committee’s review during the inquiry.

At the first meeting, the Compliance Officer will review the charge with the committee, discuss the allegations, any related issues and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry and answer any questions raised by the committee. The Compliance Officer will be present or available throughout the inquiry to advise the committee as needed.

D. Inquiry Process

The inquiry committee will have access to all research records sequestered by the Compliance Officer and may interview the Researcher, the individual reporting the misconduct and any key witnesses. The committee will determine if an investigation is warranted. It is not the responsibility of the committee to determine if misconduct definitely occurred; however if a legally sufficient admission of research misconduct is made by the Researcher, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the University will determine the next steps that should be taken without conducting any further investigation.

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

E. The Inquiry Report

The report of the inquiry committee will include the following elements:

1. The name and position of the Researcher
2. A description of the allegations of research misconduct
3. Any external funding support of the research, including amount of funding, account numbers, sponsor and grant period

4. The basis for recommending or not recommending that the allegations warrant an investigation;
5. Any comments on the draft report by the Researcher
6. Names and Titles of the inquiry committee members
7. Summary of the inquiry process used
8. List of research records reviewed
9. Summaries of any interviews
10. Statement of any other actions that should be taken if an investigation is not recommended.

F. Notification to the Researcher and Opportunity to Comment

The Compliance Officer will notify the Researcher whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment from the Researcher and allow 10 calendar days for the Researcher to submit written comments to be included in the report. This notification will include a copy of the University policy and procedures on misconduct in research.

Any comments that are submitted by the Researcher will be attached to the final inquiry report. Based upon the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the Academic Vice President with a copy to the Unit Head.

G. University Decision and Notifications

The Academic Vice President, in consultation with the Unit Head and Compliance Officer, will determine if further investigation is necessary.

If an investigation is to be conducted, the Researcher will be notified by the Academic Vice President and the Compliance Officer will take necessary steps to notify any external research funding agencies. Participants in the research project and the department chair will also be informed of the pending investigation on a “need-to-know” basis.

If an investigation is not required, conclusion of the inquiry will be documented and all records concerning the allegations will be collected by the Compliance Officer and maintained in a confidential file with access restricted to the Academic Vice President and the Compliance Officer. All records of the inquiry and allegations will be maintained for seven (7) years from the date the review was terminated, and will be available for review by external funding agencies upon written request by that agency. Diligent efforts will be undertaken, as appropriate, to restore the reputation of the Researcher whose conduct was the subject of the inquiry.

IV. Investigation

A. Initiation and Purpose

Within 30 days of the determination to conduct an investigation, the Academic Vice President will expand the Inquiry Committee to include at least five (5) tenured faculty who do not have unresolved personal, professional or financial conflicts of interest with those involved in the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues. At least three members of the committee will be from departments other than the Researcher’s department. Members of the inquiry committee may serve on the investigation committee. The Compliance Officer will be present or available throughout the inquiry to advise the committee as needed.

If the research involved any of the following three compliance areas, a member of the appropriate compliance committee will also sit on the investigation committee:

- Research with human subjects – Institutional Review Board
- Research with vertebrates – Institutional Animal Care and Use Committee
- Research with Bio-hazardous materials – BioSafety Committee

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.

The findings of the investigation must be set forth in an investigation report presented to the Academic Vice President and the Compliance Officer.

B. Notifications of Investigation

The Compliance Officer will, on or before the date on which the investigation begins, notify the Researcher in writing of the allegations to be investigated and 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 investigation that were not previously sequestered during the inquiry.

The Compliance Officer, in accordance with sponsor policies and procedures, will notify external sponsors of the research of the investigation.

The Compliance Officer will give the Researcher written notification 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.

C. Charge to the Committee and the First Meeting

The Compliance Officer will define the subject matter of the investigation in a written charge to the committee that:

1. Describes the allegations and related issues identified during the inquiry;
2. Identifies the respondent;
3. Informs the committee that it must conduct the investigation as prescribed in Paragraph D of this section;
4. Defines research misconduct;
5. Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
6. Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of evidence establishes that: (1) research misconduct, as defined in this policy, occurred, (2) the research misconduct is a significant departure from accepted practices of the relevant research community, and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and
7. Informs the committee that it must prepare a written investigation report as described in Paragraph E of this section.

The Compliance Officer will convene the first meeting of the investigation committee to 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 a copy of this statement of policy and procedures and a copy of the inquiry report.

D. Investigation Process

The investigation committee and the Compliance Officer must:

1. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
2. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
3. Interview each Researcher, the individual making the allegations 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 Researcher, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction and include the recording or transcript in the record of the investigation;
4. 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.

The investigation is to be completed within 120 calendar days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the Academic Vice President. The Compliance Officer will be responsible for notifying external sponsors of the progress of the investigation and the final findings in accordance with sponsor policies and procedures.

E. The Investigation Report

The investigation committee is responsible for preparing a written draft report of the investigation that:

1. Describes the nature of the allegation of research misconduct, including identification of the Researcher;
2. Describes and documents any and all external funding support, including account numbers, grant applications, contracts and publications of the research;
3. Describes the specific allegations of research misconduct considered in the investigation;
4. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
5. Includes a statement of findings for each allegation of research misconduct identified during the investigation;

Each statement of finding must:

- identify whether the research misconduct was falsification, fabrication, plagiarism, or unauthorized use of privileged information; and whether it was committed intentionally, knowingly or recklessly
 - summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Researcher, including any effort by the Researcher to establish by a preponderance of evidence that s/he did not engage in research misconduct because of honest error or difference of opinion, and
 - identify the person(s) responsible for the misconduct.
6. Identify whether any publications need correction or retraction; and

7. List any current support or known applications or proposals for support that the respondent has pending with external funding sources.

F. Researcher's Comments

The Compliance Officer will provide the Researcher with a draft copy of the investigative report, as well as supervised access to the evidence on which the report is based. The Researcher will be allowed 30 days from the date s/he received the draft report to submit comments to the Compliance Officer. The Researcher's comments must be included and considered in the final report.

The Compliance Officer will inform the Researcher of the confidentiality under which the draft report is made available and may require the Researcher to sign a confidentiality agreement.

G. Decision by Academic Vice President

The Compliance Officer will assist the investigation committee in finalizing the draft report, including ensuring that the Researcher's comments are included and considered, and transmit the final report to the Academic Vice President, who will determine in writing:

1. whether the University accepts the investigative report, its findings and the recommended University actions; and
2. the appropriate University actions in response to the accepted findings of research misconduct.

If the decision of the Academic Vice President varies from the findings of the investigation committee, the Academic Vice President will, as part of the written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee.

Alternatively, the Academic Vice President may return the report to the investigation committee with a request for further fact finding or analysis.

When a final decision on the case has been reached, the Compliance Officer will notify the Researcher and the individual reporting the misconduct in writing. The Compliance Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

The Academic Vice President 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 Researcher in the work, or other relevant parties should be notified of the outcome of the case.

V. Inquiry and Investigation Record Archives

The Compliance Officer is responsible for maintaining all records of proceedings for seven years after the final decision of the Academic Vice President. These records will be available for review upon written request by external funding or sponsoring agencies of the research.

VI. University Administrative Actions

The Academic Vice President will determine the appropriate actions to be taken, after consultation with the Compliance Officer. Administrative actions may include:

- a. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- b. Removal of the Researcher from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction or initiation of steps leading to possible rank reduction or termination of employment;
- c. Restitution of funds to the grantor agency as appropriate; and

- d. Other action appropriate to the research misconduct.

VII. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Researcher's university employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the university's responsibilities as set forth in this policy.

If the Researcher, without admitting to the misconduct, elects to resign his or her position after the university receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the Researcher refuses to participate in the process after resignation, the Compliance Officer and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Researcher's failure to cooperate and its effect on the evidence.

B. Restoration of the Researcher's Reputation

Following a final finding of no research misconduct, the Compliance Officer must, at the request of the Researcher, undertake all reasonable and practical efforts to restore the Researcher's reputation. Depending on the particular circumstances and the views of the Researcher, the Compliance Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the Researcher's personnel file. Any University actions to restore the Researcher's reputation should first be approved by the Academic Vice President.

C. Protection of Individual Reporting Research Misconduct, Witnesses and Committee Members

During the research misconduct proceedings and upon its completion, regardless of the outcome of the proceedings, the Compliance Officer must take all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any individual who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceedings. The Academic Vice President will determine, after consulting with the Compliance Officer and with those involved in the proceedings, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The Compliance Officer is responsible for implementing any steps approved by the Academic Vice President.

D. Actions Not Taken in Good Faith

When necessary, the Academic Vice President will determine whether actions taken by individuals reporting misconduct, by witnesses or by committee members were not taken in good faith and will determine whether any administrative action should be taken against such individuals that failed to act in good faith.

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