



POLICY & PROCEDURE DOCUMENT

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DIVISION: Academic Affairs
Research

TITLE: Research Misconduct and Non-Compliance

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AUTHORIZED BY: Dr. Robert Fischer, Provost and Vice President for Academic Affairs

I. Purpose and Scope

A. Purpose

1. Integrity in science, research, and other scholarly activities is an essential component of a viable and energetic academic community, and all members of the Western Kentucky University (WKU) community share responsibility for maintaining a climate of trust and integrity. This policy deals with university procedures for responding to allegations of research misconduct and non-compliance.

In this context, the term “**research**” is broadly interpreted and includes activities ranging from scientific experimentation to research and scholarly activity in the humanities to artistic expression and other forms of creative activity.

2. Misconduct and non-compliance in university research activities undermine the research enterprise and is harmful to the university community, the research community generally, and the public. Moreover, failure to comply with established requirements and obligations places the research enterprise and the university as a whole at risk for fines, sanctions, and other punitive consequences. Federal regulations require that WKU assume responsibility for prevention, detection, and investigation of research misconduct and non-compliance to ensure the integrity of research, the protection of the rights of research subjects and the public, and the observance of legal requirements related to federal research funding and scholarly activity.
3. Principal investigators have primary responsibility for the design, execution and management of research projects they direct, and must be vigilant in seeing that the standards of professional and ethical conduct are maintained in all phases of their

projects. In order to protect both the integrity of the research enterprise and the autonomy of the University, it is essential that all faculty, staff and students participating in research activities assume these high standards and that in the event of allegations of misconduct or non-compliance the campus administer a fair system of review. Suspected violations should be reported immediately according to the procedures described below.

4. Not all violations or serious deviations from accepted ethical practices in the conduct of research are covered by this Policy. For instance, sexual harassment, discriminatory harassment, and the violation of regulations for fiscal responsibility in research activities are covered by other specific University policies or federal regulations and are not within the scope of this Policy, but are subject to review and sanction under other applicable University policies, or applicable laws and regulations.

B. Scope

1. This Policy shall apply to all University personnel involved in research activities, including but not limited to faculty members, staff, students, research assistants and fellows, post-doctoral fellows, and other research trainees.
2. This Policy is intended to comply with the requirements set forth in the Code of Federal Regulations including, but not limited to, 42 C.F.R. Section 93 (regarding research funded by the Department of Health and Human Services) and 45 C.F.R. Section 689 Misconduct in Research –December 2015 (pertaining to research funded by the National Science Foundation). It is the responsibility of University researchers to comply with all relevant state and federal regulations, University policies, and contractual obligations.
3. *Non-Compliance.* As used in this policy statement, the term “non-compliance” refers to failure to comply with the legal and research ethics requirements governing research activities involving human subjects, vertebrate animals, and recombinant or synthetic nucleic acid molecules. Procedures required for addressing allegations of non-compliance are covered by other specific University policies or federal regulations. Allegations of non-compliance related to the protection of human subjects, the welfare of laboratory animals, or the use of recombinant or synthetic nucleic acids should be reported to the compliance manager in the WKU Office of Research Integrity or directly to the chairs of the appropriate committee. The WKU Office of Research Integrity and associated committees (e.g., Institutional Review Board, Institutional Animal Care & Use Committee, & Institutional Biosafety Committee) are responsible for establishing policies and procedures for allegations related to non-compliance, and for the prompt reporting of any serious or continuing non-compliance in accordance with institutional policies and/or state/federal regulations.
 - a. The WKU Institutional Review Board (IRB) is responsible for maintaining institutional compliance with the U.S. Office of Human Research Protections (OHRP) regulations regarding the use of human subjects in research (see policy 2.720V).
 - b. The WKU Institutional Animal Care and Use Committee (IACUC) is responsible for maintaining institutional compliance with the U.S. Office of Laboratory Animal Welfare (OLAW) regulations regarding the use of vertebrate animals in research (see policy 2.710V).

- c. The WKU Institutional Biosafety Committee (IBC) is responsible for maintaining institutional compliance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (see policy).
4. *Research Misconduct.* As used in this policy statement, the term “research misconduct” includes fabrication (making up data or results and recording/reporting them), falsification (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), or plagiarism (the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit) in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.
5. The procedures described in the remainder of this Policy will be followed when an institutional official receives an allegation of **research misconduct**. In the case of an inconsistency between this Policy and policies adopted at the department or college level, this Policy will generally govern. A finding of research misconduct requires that:
 - a. There must be a significant departure from accepted practices of the research community;
 - b. The misconduct be committed intentionally, knowingly, or recklessly; and
 - c. The allegation be proven by a preponderance of the evidence.

II. Procedure

A. Reporting Allegations of Research Misconduct

1. All members of the WKU community, including administrators, faculty, staff, and students should report any suspicion of research misconduct without delay.
2. Allegations of research misconduct should be reported to the Associate Provost for Research and Graduate Education, the Compliance Coordinator in the Office of Research Integrity, or to the dean of the college in the area in which the alleged incident(s) occurred. In order to address all allegations of research misconduct expeditiously, the University designates the dean of the appropriate college as the administrative authority to whom allegations are to be reported when the matter fully resides in said college. If the dean has a conflict of interest with a case, another administrative authority designated by the Provost and Vice President for Academic Affairs will pursue the allegation. The Provost and Vice President for Academic Affairs (or designee) will administer matters involving a broader scope than one college unit.

B. Maintenance and Protection of Records and Evidence

1. The University will take all reasonable and practical steps to obtain all records and evidence needed to conduct the misconduct proceeding and sequester them in a secure manner. In cases where records or evidence involve instruments/equipment shared by multiple users, custody may be limited to copies of the data/evidence from such instruments/equipment.

2. Where appropriate, the University will give the **respondent** (the person alleged to have committed misconduct) copies of, or reasonable, supervised access to the records.
3. All records of research misconduct proceedings must be maintained in a secure manner for 7 years (42 CFR 93.317). The institution is not responsible for maintaining the records if they have been transferred to the Department of Health and Human Services (DHHS), or if the Office of Research Integrity (ORI) has advised the institution in writing that it no longer needs to retain the records.
4. The University is responsible for providing any information, documentation, research records, or evidence requested by ORI (DHHS) to carry out its review of research misconduct that falls under the jurisdictional criteria of 42 CFR 93.102.

C. Confidentiality

The administrative authority will: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

D. Protecting Complainants, Witnesses, and Committee Members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the administrative authority, 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 Respondent

1. The administrative authority and other institutional 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.
2. During the research misconduct proceeding, the administrative authority is responsible for ensuring that respondents receive all notices and opportunities provided for in 42 CFR Part 93 and in the policies and procedures of the institution.

F. Assessment of Allegation of Research Misconduct

1. Upon receiving an allegation of research misconduct, the administrative authority 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 thus that an inquiry is warranted. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. If the allegation is within the jurisdictional criteria of 42 CFR 93.102, and the allegation falls within the definition of research misconduct in 42 CFR 93.103, an inquiry must be conducted.
2. In conducting the assessment, the administrative authority need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
3. If the administrative authority determines that an inquiry is not warranted, the Provost and Vice President for Academic Affairs will be informed of this decision in writing.

G. Research Misconduct Inquiry

1. If the administrative authority determines that the criteria for an inquiry are met, they will immediately initiate the inquiry process. At the time of or before beginning the inquiry, the administrative authority must make a good faith effort to notify the respondent in writing. On or before the date on which the respondent is notified of the allegation, the administrative authority should obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.
2. The inquiry process may be handled with or without a formal committee, at the discretion of the administrative authority. Regardless of the approach chosen, it is the responsibility of the administrative authority to ensure that the inquiry is conducted in a fair and just manner. If individuals are chosen by the administrative authority to assist in the inquiry process, they should have no real or apparent conflicts of interest with the case in question, be unbiased, and have an appropriate background for judging the issues being raised.
3. Whether a case can be reviewed effectively without the involvement of the complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant to remain anonymous.
4. The respondent will be given copies of written documents (if any) that support the allegations while maintaining protections to all involved. To ensure the safety and security of any written documents associated with the allegation, committee members will be asked to review a copy of such documents within the office of the administrative authority designated to oversee the determination of the case.

5. When the inquiry is initiated, the respondent will be reminded of the obligation to cooperate in providing the material necessary to conduct the inquiry. Uncooperative behavior is unacceptable, and may result in immediate implementation of a formal investigation. The respondent will be invited to present a written response to the allegations, and this response will become part of the case file maintained in the office of the administrative authority.
6. Due to the sensitive nature of an alleged case of research misconduct, the university will strive to resolve each case expeditiously. The inquiry phase will normally be completed and a written report of the findings filed for the institution's own record within thirty days of written notification to the respondent. If the committee anticipates that the established deadline cannot be met, a report, citing the reasons for the delay and progress to date, will be filed with the Provost and Vice President for Academic Affairs, and the respondent and appropriately involved individuals will be informed.

H. Findings of the inquiry

1. The completion of an inquiry is marked by a determination of whether or not an investigation is warranted. A written report summarizing the process and conclusion of the inquiry will be provided to the Provost and Vice President for Academic Affairs. The complainant and respondent will also be notified of the outcome of the inquiry.
2. The inquiry report must include the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) if sponsored research, name of sponsor, grant title, and grant number; (4) a brief summary of the inquiry process used; (5) the basis for recommending or not recommending that the allegations warrant an investigation; (6) any recommended actions if an investigation is not recommended; (7) any written comments provided by the respondent or complainant.
3. The scope of the inquiry is not required to and does not normally include deciding whether research misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, research misconduct may be determined at the inquiry stage if all relevant issues are resolved. The Provost and Vice President of Academic Affairs will be responsible for making the decision either to resolve the case at the conclusion of the inquiry stage or to proceed with an investigation.
4. Allegations found to require investigation will be forwarded to the investigative body discussed below. At this point, any agency sponsoring the research will be notified of a pending investigation.

5. If an allegation is found to be unjustified but has been submitted in good faith, no further formal action other than informing all involved parties will be taken. The proceedings of the inquiry, including the identity of the respondent, will be held in strict confidence to protect the parties involved. If confidentiality is breached, the university will take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. If an unjustified allegation is found to have been maliciously motivated, disciplinary actions will be recommended to the Provost and Vice President for Academic Affairs.

I. Research Misconduct Investigation

An investigation will be initiated only after an inquiry results in a finding that an investigation is warranted. The investigation's purpose is to explore further the allegations and determine whether there has been research misconduct. In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent will be informed in writing when significant new directions of investigation are undertaken. The investigation will focus on accusations of misconduct as defined previously and will examine the factual materials of each case.

J. Investigation process

1. The investigating body will be a five-person ad hoc committee appointed by the Provost and Vice President for Academic Affairs to handle the investigation based on the inquiry findings. Members of the investigative committee may be chosen from within or outside the university. Those investigating the allegations will be selected in full awareness of the closeness of their professional or personal affiliation with the complainant or the respondent. Any prospective member who has a conflict of interest in a case will not be permitted to be involved in that case. It is important, however, that the committee members have appropriate research expertise to assure a sound knowledge base from which to work.
2. Upon receipt of the inquiry finding, and determining that an investigation is warranted, the Provost and Vice President for Academic Affairs will initiate the investigation promptly. The complainant and respondent will be notified in writing of the investigation; the written summary of the inquiry stage will be included with this notification. All involved parties are obligated to cooperate with the proceedings in securing additional data/evidence related to the case. All necessary information will be provided to the respondent in a timely manner to facilitate the preparation of a response. The respondent will have the opportunity to address the charges and evidence in detail. The respondent may seek outside advice as needed during the investigation but may not be formally represented by legal counsel during investigative proceedings.
3. In the interim, the university will, if necessary, act to protect the health and safety of research subjects, patients, students, or any other persons at risk. Administrative action could range from complete suspension to slight restrictions in the activities of the respondent. Interim administrative action will be taken in full awareness of how it might affect other individuals and the ongoing research within the institution.
4. The written record for the investigative stage will be handled in the same manner as for the inquiry stage, i.e., one copy of the record will be given to the respondent, a second, maintained by the Provost and Vice President for Academic Affairs, will be available for inspection by the committee.

5. If the allegation is within the jurisdictional criteria of 42 CFR 93.102, and the allegation falls within the definition of research misconduct in 42 CFR 93.103, the Office of Research Integrity must also be notified within 30 days of the decision to proceed with an investigation.
6. The university will attempt to complete an investigation within 120 days. If the deadline cannot be met, an interim report will be submitted by the committee to the Provost and Vice President for Academic Affairs with a request for an extension.

K. Findings of the Investigation

The findings of the investigative committee will be submitted in writing to the Provost and Vice President for Academic Affairs. The respondent will receive the full report of the investigation.

L. Appeal/Final Review

1. In the event of a finding of research misconduct, the university will provide the respondent with an appeal opportunity. A written appeal of the investigative committee's decision is to be addressed to the Provost and Vice President for Academic Affairs or designee and should be restricted to the body of evidence already presented.
2. An appeal must be filed within two weeks of a finding of research misconduct. If the respondent does not file an appeal, the investigative committee's finding becomes final.
3. The Provost and Vice President for Academic Affairs will normally provide a decision on an appeal within sixty days. The Provost may consult with other in considering the appeal. If the deadline cannot be met, the respondent will be notified in writing the reasons for the delay. The decision rendered on the appeal will be final.

M. Resolution

1. No Finding of Research Misconduct

When the investigation finds no support for allegations of research misconduct, all federal agencies, sponsors, or other entities initially informed of the investigation will be notified promptly by the Provost & Vice President for Academic Affairs. The findings of the investigation will be retained in a confidential and secure file within the office of the Provost and Vice President for Academic Affairs. If unjustified allegations of misconduct were found to have been maliciously motivated, appropriate disciplinary actions will be recommended to the Provost and Vice President for Academic Affairs. If the allegations; however incorrect, were found to have been made in good faith, no disciplinary measures will be taken and efforts will be made to prevent retaliatory actions.

2. Finding of Research Misconduct

A finding of research misconduct made under this policy requires that:

- There be a significant departure from accepted practices of the relevant research community; and

- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation is proven by a preponderance of the evidence.

In the event of a finding of research misconduct, the investigative committee will provide the Provost and Vice President for Academic Affairs with a recommendation as to the agencies to be notified. All federal agencies, sponsors, or other entities initially informed of the investigation will be notified promptly of the finding of research misconduct. Consideration will also be given to formal notification of other involved parties. The following list of such parties is illustrative but not exhaustive.

- Co-authors, co-investigators, collaborators
- Editors of journals in which fraudulent research was published
- Sponsoring agencies and funding sources with which the individual has been affiliated
- Professional societies

N. Disciplinary Action

1. In the event of a research misconduct finding, the investigative committee will provide the Provost and Vice President for Academic Affairs with a recommendation as to the disciplinary action to be taken. University disciplinary action will be in proportion to the misconduct. The following list of possible university actions is illustrative:
 - Removal from a particular research project
 - Withdrawal or correction of all pending or published abstracts and papers emanating from research where research misconduct was found
 - Letter of reprimand
 - Special monitoring of future work
 - Suspension
 - Salary reduction
 - Probation
 - Termination of employment
 - Other action appropriate to the research misconduct
2. The recommendation of the Provost and Vice President for Academic Affairs will be forwarded to the President for final action. If the President does not agree with the recommendation, an alternative course of action may be taken and an explanatory statement must be filed with all involved parties including the respondent.
3. The termination of a respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate research misconduct proceedings or otherwise limit the institution's responsibilities under 42 CFR Part 93.

O. Special Considerations for Sponsored Research

The institution is responsible for notifying the funding agency or sponsor if it is ascertained at any stage of the inquiry or investigation that any of the following conditions exist:

- There is an immediate health hazard involved;
- There is an immediate need to protect Federal funds or equipment;

- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as co-investigators and associates, if any;
- It is probable that the alleged incident is going to be reported publicly;
- There is a reasonable indication of possible criminal violation. In that instance, the institution must inform the funding agency within 24 hours of obtaining that information.

III. Reason(s) for Revision

August 2021

Non-substantive changes resulting from fifth year review in accordance with Policy 0.000V.

IV. Related Policies

Policy 2.000V Research
Policy 2.010V Extramural Contracts and Grants
Policy 2.710V Policy on Use of Animals
Policy 2.720V Policy on Research on Human Subjects

V. Applicable Regulations and Guidelines Used to Develop This Policy

42 CFR Part 93: Public Health Service Policies on Research Misconduct

45 CFR Part 689 Misconduct in Research –December 2015 (pertaining to research funded by the National Science Foundation). <https://www.gpo.gov/fdsys/pkg/CFR-2012-title45-vol3/pdf/CFR-2012-title45-vol3-part689.pdf>

<https://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations>