

Policies and Procedures: Research Related Policies

Ethical Standards in Research

A. Institutional Goals

It is in the best interest of the public and of academic medicine to prevent misconduct in research and to deal effectively and responsibly with an instance when misconduct is suspected or substantiated. The maintenance of public trust requires adherence to the ethical principles that govern scientific research, and is the responsibility of the faculty, staff and administration of an academic medical center. This policy provides the procedures under which possible misconduct by people doing research will be investigated and resolved. The policy applies to fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Misconduct does not include honest error, honest differences in interpretation or judgments of data, or disputes regarding authorship.

B. Institutional Policies

1. Prevention of misconduct in research: The Institution strives to provide an open and stimulating environment for creativity and individual thought where a faculty member will develop independently and productively. It is intended that this climate will promote high ethical standards and enhance the research process. It is recognized that there is a near certainty that falsified, fabricated, or plagiarized data will be detected. To further discourage impropriety, Institutional policies and procedures relating to misconduct have been adopted.
2. Report of misconduct: The Institution has adopted the procedures described below so that a report of possible scientific misconduct may be investigated and resolved in an expeditious, fair, thoughtful, confidential, and judicious manner.
3. Individual responsibilities: Each investigator has responsibilities relating to ethical conduct of research. These include awareness of Institutional policy; supervision of others; maintaining research records; collaborative efforts; and publication and other dissemination of research findings.
 - a. The faculty is encouraged to discuss research ethics and to heighten awareness of problems of misconduct in science.
 - b. The quality of research is more important than is quantity as a measure of productivity.
 - c. The conduct of research is the responsibility of the principal investigator [and co-investigator(s)]. These individuals supervise support personnel and are in turn supervised by the section head or department chairman. This policy applies to all individuals performing research activities, including faculty and support personnel. Large research teams and multi-institutional research teams require particular attention to the establishment of appropriate levels of supervision.
 - d. Research data will be recorded and appropriately authenticated by the investigator at the time the research is conducted. These

data will be maintained in accordance with the Data Ownership policy of the Institution.

- e. Responsibilities related to authorship are addressed in the Authorship policy of the Institution. Papers and abstracts with joint authors will be the work of those who have contributed significantly to the research. Each of the authors accepts the responsibility for the quality and veracity of the work reported.
4. Good faith report: Institutional employees who receive or learn of a report of scientific misconduct will treat the complainant with fairness and respect and, when the report has been made in good faith, will take reasonable steps to protect the position and reputation of the complainant and other individuals who cooperate with the Institution against retaliation. Employees will immediately report any real or apparent retaliation to the Research Integrity Officer.
5. Interim administrative actions: Following a good faith report of scientific misconduct, the Institution will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

C. **Applicability**

These policies and procedures are specific for Public Health Service (PHS) supported research (e.g., NIH, CDC, FDA), as required by 42 CFR 50.101. The Institution's policies and procedures will be applied in like manner to all sponsored research. That is, all sponsored research, whether federal or non-federal, is subject to these procedures. Reporting requirements vary as to sponsor (e.g. NSF, DOD, NASA, USDA).

D. **Definitions**

- a. *Complainant* means a person who makes a report of possible scientific misconduct.
- b. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- c. *Deciding Official* means the Institutional official (Dean or a designee) who makes final determinations on reports of scientific misconduct and any responsive Institutional actions.
- d. *Good faith report* means a report made with the honest belief that scientific misconduct may have occurred. A report is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the report.
- e. *Inquiry* means gathering information and initial fact-finding to determine whether a report or apparent instance of scientific misconduct warrants an investigation.
- f. *Institution* means Wake Forest University School of Medicine.

- g. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.
- h. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U. S. Public Health Service.
- i. *PHS* means the U. S. Public Health Service, an operating component of the DHHS.
- j. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefor.
- k. *Research Integrity Officer* means the Associate Dean for Research, the Institutional official responsible for assessing reports of scientific misconduct and determining when such reports warrant inquiries and for overseeing inquiries and investigations.
- l. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of a report of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.
- m. *Respondent* means the person against whom a report of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
- n. *Retaliation* means any action that adversely affects the employment or other Institutional status of an individual that is taken by the Institution or an employee because the individual has in good faith, made a report of possible scientific misconduct or of inadequate Institutional response thereto or has cooperated in good faith with an investigation of such report.
- o. *Scientific misconduct* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest

differences in interpretation or judgments of data, or disputes regarding authorship.

E. Procedures when Possible Misconduct is Reported

0. **Initial report:** The initial report of possible misconduct will be brought to the attention of the Research Integrity Officer, who will determine if the report requires further attention. To accomplish this, the Research Integrity Officer may consult with the Institutional Legal Department, and/or other appropriate individuals to decide if the report warrants further inquiry. The Research Integrity Officer may decide to appoint a fact-finding team to assess and advise. If the report is frivolous, then the Research Integrity Officer will notify the complainant of the disposition of the case.

1. **Inquiry:** If the Research Integrity Officer determines that the report of misconduct warrants further inquiry, he will notify the respondent as well as the departmental Chairman of the misconduct report and immediately secure all original research records and material relevant to the report. Thus begins the inquiry portion of the process. The Research Integrity Officer will appoint an inquiry committee, consisting of three faculty members at the level of Associate Professor or above who have the necessary expertise to evaluate the evidence, and who have no personal responsibility for the research under review or real of apparent conflict of interest with the matter. A representative of the Office of Research will provide administrative assistance to the committee. The Institutional Legal Department will be available to advise the committee. This review must be completed within 60 calendar days from notification of the respondent.

2. **Report to ORI:** In the case of PHS-sponsored research, the Research Integrity Officer shall notify the Director, Office of Research Integrity (ORI) prior to completion of the inquiry or investigation when:
 - a. There is an immediate health hazard involved;
 - b. There is an immediate need to protect Federal funds or equipment;
 - c. There is an immediate need to protect the interests of the complainant or of the respondent as well as his/her co-investigators and associates, if any;
 - d. It is probable that the reported incident is going to be reported publicly; or,
 - e. There is a reasonable indication of possible criminal violation. In that instance, the Institution must inform ORI within 24 hours of obtaining that information. ORI will immediately notify the Office of the Inspector General, DHHS.

If the Research Integrity Officer plans to terminate an inquiry or investigation without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the

planned termination to ORI, including a description of the reasons for the proposed termination.

3. Inquiry report: The committee will prepare a written report for review by the Research Integrity Officer. The report shall describe what evidence was received, summarize relevant interviews, and include the conclusions of the review. The respondent shall be given a copy of the report. If the respondent comments on that report, it will be made part of the record. If the review requires longer than 60 days to complete, the report shall include documentation of the reasons for exceeding the 60-day period.
4. Decision not to investigate: After the inquiry, the Research Integrity Officer will provide the Deciding Official with the inquiry report; the Deciding Official will determine whether the report warrants more thorough investigation. If the Deciding Official determines that it is not necessary to pursue the misconduct report by undertaking an investigation, the Deciding Official will document the reasons for this decision and the findings from the inquiry. When a formal investigation is found not warranted, the records shall be sufficiently detailed to permit later assessment for that determination. Records documenting an inquiry on reports of possible misconduct in connection with PHS-sponsored research shall be securely maintained for at least 3 years after termination of the review, and upon request, shall be provided to the Director, ORI. Diligent efforts will be undertaken, as appropriate, to restore the reputations of the respondent whose conduct was the subject of the inquiry.
5. Notification of investigation: If it is determined that there is sufficient basis for pursuing the report of misconduct, the Research Integrity Officer will inform the respondent of the pending investigation. All participants in the research project and the appropriate department chairman will also be informed of the pending investigation. In the case of PHS-sponsored research, the Research Integrity Officer shall notify the Director, ORI, upon a determination that an investigation is warranted on or before the date the investigation begins.
6. Investigation: Committee composition and charge: The Deciding Official shall immediately appoint an ad hoc committee to conduct a prompt and thorough investigation of the reported misconduct and determine whether there has been scientific misconduct. The Committee will consist of at least three individuals, the majority being academic senior level faculty from at least two departments other than the involved department, who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary and appropriate expertise to evaluate the evidence and issues related to the misconduct report, to interview the principals and key witnesses, and to conduct the investigation. The majority of the faculty members of the Committee must have active, peer reviewed extramurally funded research programs, and one of the faculty will serve as Chairman. The Institutional Legal Department will serve to advise the committee. The investigation will proceed in a confidential manner

within 30 days of the completion of the inquiry. The investigation will ordinarily be completed within 120 days of the initiation of the investigation (including submission of the final report to ORI). In the case of PHS-sponsored research, if additional time is necessary, a request may be made to ORI which shall include an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps.

- a. The Research Integrity Officer will sequester any additional pertinent research records that were not previously sequestered during inquiry. The Research Integrity Officer will also notify the respondent as soon as reasonably possible after the determination is made to open an investigation.
 - b. During the investigation, consideration will be given to the review of all research with which the respondent is involved, including but not limited to, relevant research data and proposals, publications, correspondence, telephone call records, and purchase and utilization records of supplies and other research materials.
 - c. The respondent and any collaborators or supervisors whose role in the reported misconduct has been placed in question will be afforded the opportunity to respond and provide additional information.
 - d. The respondent will be provided an adequate opportunity to explain and defend his/or her actions, to provide a written statement, and to be advised by counsel.
 - e. Complete summaries of interviews shall be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file. Detailed minutes shall be kept of all Committee meetings as part of the investigatory file.
 - f. The Committee will prepare a report that will describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, the basis for the findings, and an accurate summary of the views of any individual(s) found to have engaged in scientific misconduct, as well as a description of any sanctions taken by the Institution.
7. Report of the investigation committee: The Committee will submit a draft investigation report to the Research Integrity Officer, who will provide the respondent with a copy of the draft report for comment and rebuttal. The respondent will be allowed 7 days to review and comment on the draft report. The respondent's comments will be attached to the final report. In addition, the Research Integrity Officer will provide the complainant with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The findings of the final report should take into account any comments by either the respondent or the complainant in addition to all other evidence. The Committee will then present a final written confidential report to the Deciding Official with regard to the existence of misconduct. The investigatory file shall contain documentation to substantiate the Committee's findings. This report,

in the case of PHS-sponsored research, shall be submitted to the Director, ORI, within 120 days of the initiation of the investigation. The documentation supporting this report will be maintained and made available to the Director, ORI. If the Committee is unable to make a definitive determination, the Chairman shall so notify the Deciding Official. The Deciding Official may then accept the report's findings and recommendations, vary the decision, or return the report to the Committee for further fact-finding or analysis.

8. Action following investigation:

- a. Finding of misconduct: Based upon the report of the Committee, if the Deciding Official determines that there has been misconduct, the sponsoring agency (ORI in the case of PHS-sponsored research) will be notified in writing of the findings of the investigation and any appropriate financial restitution will be made.

All pending abstracts and papers emanating from improper research will be withdrawn. Editors of journals will be notified in writing when abstracts and papers have appeared affected by improper research. Institutions and sponsoring agencies with which the individual has been affiliated will be notified if there is reason to believe that the validity of previous research might be questionable.

The Dean may take appropriate action with respect to faculty members and others whose scientific misconduct is substantiated. Such action may include, without limitation, removal from a specific project; letter of reprimand; special monitoring of future work; probation; suspension; salary reduction; demotion; or termination. In consultation with the Institutional Legal Department, institutional administrators may release appropriate information to the public about the incident, particularly when public funds were used in supporting the research.

- b. Finding of no misconduct: If the misconduct is not substantiated by a thorough investigation, diligent efforts will be undertaken to restore the reputation of the respondent and others whose conduct has been investigated. The sponsoring agency (ORI in the case of PHS-sponsored research) will be immediately notified in writing. In addition, appropriate disciplinary action will be taken against any party whose involvement in leveling unfounded charges was demonstrated to have been malicious or intentionally dishonest.
9. Review: After an investigation, the Committee will review the incident and make recommendations to the Dean and Department Chairmen for strengthening research integrity and for the development of measures designed to prevent similar incidents.

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