

Northwestern Health Sciences University	
Policy: Misconduct in Science Policy	Effective Date: March 2020
	Revision Date: January 2021

Purpose

This policy establishes procedures for reporting and investigating allegations of scientific misconduct, and for the required notifications to federal agencies of such allegations and investigations.

Scope

This policy shall apply to any individual at Northwestern Health Sciences University participating in research funded by the Public Health Service (PHS) or National Science Foundation (NSF). Collaborators, subrecipients, and subcontractors from other academic, not-for-profit, or commercial entities must also comply with this policy or provide an institutional certification stating that they are in compliance with Federal policies regarding scientific misconduct.

Policy

Introduction

Each member of Northwestern Health Sciences University has a responsibility to foster an environment which promotes intellectual honesty and integrity, and which does not tolerate misconduct in any aspect of research or scholarly endeavor. Scientific misconduct is extremely troubling--in spite of its infrequency--because when it occurs, it is destructive of the standards we attempt to instill in our students, of the esteem in which academic science in general is held by the public, and of the financial support of the government and other sponsors for academic scientific enterprise. Therefore, this policy has been established to emphasize the importance of integrity in research.

This policy does not supplant nor obviate any provisions of the University's policy on Review and Grievance Procedures for Faculty as stated in the Faculty Handbook, but instead addresses issues of scientific misconduct for participants in PHS and/or NSF projects. Also, this policy addresses only scientific misconduct. Allegations or suspicions of misconduct outside the scope of this policy should be directed to the appropriate department head; the process of investigation and reporting obligations may differ from those required for scientific misconduct cases.

Applicable regulations

The U. S. Public Health Service (PHS) regulations in 42 CFR Part 93 became effective June 16, 2005, and carry the weight of federal regulation. Both NSF and National Institutes of Health (NIH) require that policies and procedures are developed to ensure:

- an impartial process for receipt and disposition of allegations of scientific misconduct;
- protection of the integrity of the research, research subjects, and the public;
- observance of legal requirements and responsibilities;
- notification to sponsoring agency of allegations, inquiries, and investigations as prescribed;

- notification to the respondent consistent with time limits defined by the final rule;
- protection of the confidentiality of respondents, complainants, and research subjects, consistent with Section 93.108.1; and,
- maintenance of records relating to this policy, for at least three years following the termination of a given project.

While both PHS and NSF recognize that the primary responsibility for the prevention, detection, and investigation of misconduct rests with the awarded institution, they both retain the right to initiate their own investigations at any time.

Definitions

Allegation: Disclosure of possible research misconduct through any means of communication.

Inquiry: Information-gathering and preliminary fact-finding to determine whether an allegation or an apparent instance of misconduct warrants an investigation. The outcome of an inquiry is a determination as to whether or not an investigation is to be conducted.

Investigation: A formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.

Procedures: Response to an allegation of misconduct in research will be carried out promptly by conducting an inquiry and, if the findings from the inquiry determine it to be necessary, by conducting a full investigation.

Scientific Misconduct: Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. Also included as scientific misconduct for this purpose is retaliation of any kind against a person who, acting in good faith, reported or provided information about suspected or alleged misconduct.

Response to an Allegation

Any allegation of misconduct should immediately be brought in written form to the attention of the Vice President of Academic Affairs/Chief Academic Officer.

Procedure

Inquiry

Upon receiving a report of research misconduct, the Vice President of Academic Affairs/Chief Academic Officer will determine if:

1. it meets the definition of research misconduct in 42 CFR Section 93.103
2. it involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b); and
3. the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If the Vice President of Academic Affairs/Chief Academic Officer determines that an inquiry is warranted,

they will do so within 60 days of the initial complaint. The initial inquiry is not a formal hearing, but a gathering and reviewing of facts to determine whether a full investigation is warranted or, alternatively, whether the facts do not sufficiently support the need for a full investigation. The Vice President of Academic Affairs/Chief Academic Officer may appoint an ad hoc committee to assist with the inquiry and make recommendations.

The Vice President of Academic Affairs/Chief Academic Officer will maintain an inquiry report, containing sufficiently detailed documentation to permit a later assessment, if necessary, of the reasons for determining that an investigation was not warranted. The inquiry report will include:

- 1) the name and position of the respondent
- 2) description of the allegations of research misconduct
- 3) the PHS support involved, including grant numbers, grant applications, contracts and publications listing PHS support
- 4) the basis for recommending that alleged actions warrant investigation
- 5) any comments on the report by the respondent or the complainant

If the inquiry requires longer than 60 days to complete, documentation of reasons for the delay will be included in an inquiry report. Records will be kept for at least three years and shall, upon request, be provided to authorized funding agency personnel.

Based on the charge, as well as response of the respondent and recommendations of the ad hoc committee (if any), the Vice President of Academic Affairs/Chief Academic Officer shall make a written determination of whether an investigation is warranted.

If it is determined that insufficient grounds have been presented to warrant further pursuit of the allegation, the respondent will be notified and subject to no discipline.

If it is determined that an investigation is warranted, one will commence within 30 calendar days. Written notice of decision to open an investigation will be submitted to the Office of Research Integrity prior to the date on which an investigation begins. The respondent will be notified of the investigation in writing.

Investigation

The purpose of the investigation is to explore further the allegations reviewed during the inquiry to determine if misconduct has actually occurred. The investigation will begin within 30 calendar days of the determination that one is needed, with best efforts to complete the investigation within 120 calendar days of the date on which it began. This includes conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to Office of Research Integrity (ORI). An extension from ORI may be requested in writing. The investigation will be conducted in confidence so that the risk to the reputation of the person under inquiry is minimized and in accordance with Section 93.108.1.

The investigation will be conducted by a committee which includes individuals with knowledge and background appropriate to carry out the investigation. In appointing the committee, the Vice President of Academic Affairs/Chief Academic Officer will screen potential committee members for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection. Committee members will be expected to state in writing that they have no conflicts of interest.

This committee will be given the notice of the complaint and charged to investigate the matter. In its investigation, the committee will be expected to do the following:

- (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 the allegations;
- (2) 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 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 investigation;
- (3) Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion; and
- (4) Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310.

An institutional investigation report will be produced in writing, which will:

- (1) Describe the nature of the allegations of research misconduct;
- (2) Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;
- (3) Describe the specific allegations of research misconduct considered in the investigation;
- (4) Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI;
- (5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. The report should also describe any relevant records and evidence not taken into custody and explain why.
- (6) Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, (i) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard, (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations, (iii) identify the specific PHS support; (iv) identify any publications that need correction or retraction; (v) identify the person(s) responsible for the misconduct, and (vi) list any current support or known applications or proposals for support that the respondent(s) has pending with non-PHS Federal agencies; and
- (7) Include and consider any comments made by the respondent and complainant on the draft investigation report.

All relevant research records and records of the research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews, will be maintained and provided to ORI upon request.

Notice to Respondent

During the research misconduct proceeding, respondents shall be provided the following:

Initiation of Inquiry. Prior to or at the beginning of the inquiry, we shall provide the respondent(s) written notification of the inquiry and contemporaneously sequester all research records and other evidence needed to conduct the research misconduct proceeding. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.

Comment on Inquiry Report. We shall provide the respondent(s) an opportunity to comment on the inquiry report in a timely fashion so that any comments can be attached to the report.

Results of the Inquiry. We shall notify the respondent(s) of the results of the inquiry and attach to the notification copies of the inquiry report and these institutional policies and procedures for the handling of research misconduct allegations.

Initiation of Investigation. Within a reasonable time after our determination that an investigation is warranted, but not later than 30 calendar days after that determination, we shall notify the respondent(s) in writing of the allegations to be investigated. We shall give respondent(s) written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

Scheduling of Interview. We will notify the respondent sufficiently in advance of the scheduling of his/her interview in the investigation so that the respondent may prepare for the interview and arrange for the attendance of legal counsel, if the respondent wishes.

Comment on Draft Investigation Report. We shall give the respondent(s) a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent(s) that any comments must be submitted within 30 days of the date on which he/she received the draft report. We shall ensure that these comments are included and considered in the final investigation report.

Appeal. A person who has been disciplined may file an appeal with the Vice President of Academic Affairs/Chief Academic Officer within 120 calendar days, or longer if ORI grants an extension in writing for good cause. This 120 day deadline does not apply to institutional termination hearings that are conducted separately from the appeal process. The respondent may also contest ORI findings of research misconduct and/ or proposed HHS administrative action. NWHSU will fully cooperate with ORI during review, including the provision of any necessary records and evidence related to the appeal. After a final decision is reached on the appeal, the accused and all others who were informed about the investigation will be promptly and formally notified of the results.

As in the initial inquiry, it is expected that those consulted will maintain the confidence of the consultations. Complete summaries of interviews with witnesses shall be prepared, provided to the interviewed party for comment or revision, and included as a part of the investigatory file. All records of the investigation will be maintained under the control of the Vice President of Academic Affairs/Chief Academic Officer.

The investigation will be conducted as expeditiously as possible with a goal of being completed within 120 days. This period includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, considering and addressing of any written comments received from the respondent related to the report of findings, and submitting a final report to the Vice President of Academic Affairs/Chief Academic Officer for decision and submission to the Office of Research Integrity or the appropriate agency.

To the extent allowed by law, NWHSU will maintain the identity of respondents and complainants

securely and confidentially and shall not disclose any identifying information, except to: (1) those for whom this information is necessary to conduct a thorough, competent, objective and fair research misconduct proceeding; and (2) ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need this information to carry out the research misconduct proceeding.

Findings of the Investigation

After receiving the report with findings of fact from the committee, the Vice President of Academic Affairs/Chief Academic Officer will reach a decision and determine if disciplinary action will be taken against the respondent.

Institutional actions in response to findings of research misconduct may include reprimand, requirement to correct or retract publications affected by the findings of the investigation, a special program for monitoring future research activities, removal from a project, reduction in salary and/or rank, probation, suspension, or termination of employment. The severity of the discipline shall not exceed a level that is reasonably commensurate with the seriousness of the cause.

NWHSU will cooperate with and assist ORI and Health and Human Services (HHS), as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS.

Notification of Research Sponsors

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of our finding that an investigation is warranted), we shall provide ORI with the written finding by the Vice President of Academic Affairs/Chief Academic Officer and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a). Upon a request from ORI we shall promptly send them: (1) a copy of our institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider.

We shall promptly provide to ORI after the investigation: (1) A copy of the investigation report, all attachments, and any appeals; (2) A statement of whether the institution found research misconduct and, if so, who committed it; (3) A statement of whether the institution accepts the findings in the investigation report; and (4) A description of any pending or completed administrative actions against the respondent.

Both PHS and NSF have the right to impose additional sanctions, beyond those applied by the institution, upon investigators or institutions, if they deem such action appropriate in situations involving funding from their respective agency.

Maintenance and Custody of Research Records and Evidence

We shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

(1) Either before or when we notify the respondent of the allegation, we shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so

long as those copies are substantially equivalent to the evidentiary value of the instruments.

(2) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records.

(3) Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (1) above.

(4) We shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a) (copy attached), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93 (copies attached), whichever is later, unless we have transferred custody of the records and evidence to HHS, or ORI has advised us that we no longer need to retain the records.

Interim Protective Actions

At any time during a research misconduct proceeding, we shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

Notifying ORI of Special Circumstances that may Require Protective Actions

At any time during a research misconduct proceeding, we shall notify ORI immediately if we have reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(2) HHS resources or interests are threatened.

(3) Research activities should be suspended.

(4) There is a reasonable indication of violations of civil or criminal law.

(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(6) We believe the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

(7) We believe the research community or public should be informed.

Restoring Reputations

Respondents. We shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that we do so.

Complainants, Witnesses, and Committee Members. We shall undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members.

Cooperation with ORI

We shall cooperate fully and on a continuing basis with ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under our control or custody, or in the possession of, or accessible to, all persons that are subject to our authority.

We will report to ORI any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.