



Policy and Procedure Governing Investigation of Research Misconduct (2019)

Preamble

North South University (NSU) faculty, staff, and students are accountable for the research integrity of all biomedical and behavioral research conducted, with the expectation that all investigators act in compliance with NSU governing policy on human subjects research and animal care and use in research in particular. All research falling within these two main categories of research are subject to review for scientific merit by the designated school Scientific Review Committee (SRC) and subsequently, where warranted, by the university's Institutional Review Board/Ethics Review Committee (IRB/ERC) or the university's Animal Care and Use Committee (IACUC).

Any individual within or outside the university community may, without prejudice as to any untoward penalty, communicate an allegation of research misconduct to the designated Institutional Official (IO) and/or to the Director, Office of Research-NSU. It is the responsibility of university authority to investigate such allegations through appropriate inquiry and investigation, and then to dispose of any allegation according to procedure stipulated within this policy governing research misconduct.

Inasmuch as NSU follows an American model of higher education, standards common to American institutions of higher education are adapted here, including research misconduct policy as adopted by the Office of Research Integrity of the Department of Health and Human Services, as articulated and published in the *Federal Register*, Vol. 70, No. 94, dated 17 May, 2005, "Rules and Regulations," Subpart A, §§ 93.100 ff. (Where statements in following sections are given in quotation marks or in adapted paraphrase, the source is this published version of the regulation or the text of "Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct, 42 CFR Part 93., online version accessible at <https://ori.hhs.gov/sites/default/files/requirements.pdf>).

Basic Definition of Research

'Research' means "a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research), e.g., relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied." The same criteria shall apply in the case of any and all behavioral research normally conducted in the social sciences and following discipline-specific research methods.



Basic Definition of Research Misconduct

In general, 'research misconduct' shall be understood to occur when an investigator violates, whether through negligence or deliberate intent, (1) national scientific and/or ethical guidelines as established by Bangladesh governmental regulatory authority, (2a) NSU human subjects research protection policy, or (2b) NSU animal care and use policy, or (3) any other policy that NSU may promulgate, that governs the specific research in question. Research misconduct, therefore, occurs generally when:

- a. carried out contrary to the public interest, including here public safety, public health, and public welfare; as well as when,
- b. carried out contrary to NSU institutional interests to assure the public and the research community that NSU investigators are performing their professional duties consistent with national and international standards of responsible conduct of research.

In this sense, then, 'research misconduct' can involve specifically any one or combination of the following actions undertaken during *proposing*, *performing*, *reviewing*, or in *reporting* research, research training, or activities related to research or research training:

1. Any breach of SRC-approved, IRB/ERC-approved, or IACUC-approved research protocol(s);
2. Misrepresentation of research investigator professional qualifications and/or professional experience;
3. Deliberate plagiarism and misrepresentation of due credit for authorship; 'plagiarism' means "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit;"
4. Manipulation, falsification, or fabrication of research results and/or records produced in the course of research, contrary to standards expected of research data safety and monitoring;
(a) 'Fabrication' means "making up data or results and recording or reporting them;"
(b) 'Falsification' means "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;"
5. Deliberate mismanagement (fiscal impropriety) of institutionally supported (intramural) and/or externally sponsored (extramural) research funds that were disbursed in a research grant, contract, or inter-institutional cooperative/collaborative agreement.
6. Research misconduct "does not include honest error or differences of opinion" such as are matters of reasonable disagreement about scientific facts and/or interpretation of those facts.



Research Misconduct Investigation Committee

The Director, Office of Research-NSU, shall constitute a Research Misconduct Investigation Committee (RMIC) on an ad hoc basis for the purpose of conducting a formal investigation into allegations of research misconduct. This committee shall be constituted only after a preliminary inquiry conducted by the Director, Office of Research, determines that there are reasonable grounds for a formal investigation. The Director, Office of Research-NSU, shall appoint the Chairperson of the committee and issue a formal written directive to initiate a formal investigation.

Other Definitions of Terms

Allegation

'Allegation' means "a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication" to an NSU institutional official, including the NSU Institutional Official (IO) as designated in NSU policies and/or the Director, Office of Research-NSU.

Research record

'Research record' means "the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to NSU or an NSU institutional official by a respondent in the course of the research misconduct proceeding."

Complainant

'Complainant' means "a person who in good faith makes an allegation of research misconduct."

Respondent in Research Misconduct Investigation

'Respondent', for purposes of a research misconduct investigation undertaken under NSU authority, means any research investigator who is formally alleged to have engaged in research misconduct as defined above.

Inquiry

'Inquiry' means "preliminary information-gathering and preliminary fact-finding."



Investigation

'Investigation' means "the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions." Any investigation must be a "thorough, competent, objective, and fair response to allegations of research misconduct." Further, institutional authority must assure that precautions are taken "to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses." Further, consistent with standards of judicious assessment, "all reasonable and practical efforts, if requested and appropriate," are to be taken "to protect and restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made." Similarly, and with due parity, "all reasonable and practical efforts" are to be made "to protect or 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."

Research misconduct proceeding

'Research misconduct proceeding' means "any actions related to alleged research misconduct taken under this policy, including but not limited to, allegation assessments, inquiries, investigations, oversight reviews, hearings, and administrative appeals."

Institution

'Institution' means, with reference to this policy, North South University, inclusive of biomedical and behavioral research laboratories, research centers and institutes wherein or under whose administrative authority research occurs.

Institutional member

'Institutional member' means "a person who is employed by, is an agent of, or is affiliated by contract or agreement" with North South University. This may include all core faculty, researchers, research coordinators, postdoctoral fellows and other fellows, laboratory technicians, clinical technicians, graduate and/or undergraduate research associates/assistants, volunteers, agents, contractors, subcontractors, recipients of intramural or extramural grants or awards.

Evidentiary Standard

1. "*Burden of Proof*": Whenever an investigation for research misconduct is authorized, it is to be understood that the NSU Office of Research-NSU, as



- the designated investigating authority, has “the burden of proof for making a finding of research misconduct.”
2. *“Standard of Proof”*: An institutional finding of research misconduct must be established by:
 - a. a preponderance of the evidence; ‘preponderance of the evidence’ means “proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.”
 - b. a manifest preponderance of evidence that a “significant departure from accepted practices of the relevant research community,” e.g., as represented by best practices concerning research methodology, has occurred;
 - c. an intentional, knowing, reckless, or otherwise negligent engagement in misconduct;
 3. *Status of Research Records*: “The destruction, absence of, or respondent’s failure to provide research records adequately documenting the questioned research is evidence of research misconduct” where NSU investigating authority establishes “by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community.”
 4. *Respondent Burden*:
 - a. “The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised.”
 - b. Further, “The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.”
 - c. In determining whether NSU, as investigating authority, “has carried the burden of proof imposed” by this policy, “the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

Evidence

‘Evidence’ means “any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact” according to the standard of proof stipulated in this policy.



Rule of Interpretation

Consistent with the scope of research misconduct defined above, any interpretation of this policy must (1) assure that public safety, public health, and public welfare have been reasonably and responsibly taken into account, and (2) further the policies of the NSU Office of Research that govern responsible conduct of research.

Confidentiality

Consistent with university policy, practice, and applicable Bangladesh laws and regulations, NSU investigating authority shall assure that “disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know [in order to carry out the research misconduct proceedings], consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law.”

Administrative action

‘Administrative action’ means any action taken by NSU investigating authority in response to a research misconduct proceeding consistent with the institution’s operative policy governing research misconduct investigation and/or other applicable policy, regulation, or procedure governing human subjects research, animal care and use, and/or grant management, contracts, and inter-institutional cooperative/collaborative agreements.

Charge Letter

‘Charge letter’ means “the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct” and any NSU investigative authority administrative actions.

Notice

‘Notice’ means “a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee.”

Good faith

‘Good faith’ “as applied to a complainant or witness, means having a belief in the truth of one’s allegation or testimony that a reasonable person in the complainant’s or witness’s position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially



for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.”

Hearing

‘Hearing’ means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest OR-NSU findings of research misconduct and NSU administrative actions until such time as the Institutional Official (IO) so designated under NSU policy issues a recommended decision.

Maintenance and custody of research records and evidence

NSU, as the responsible legal entity for supported research, has a continuing obligation to ensure that it maintains adequate records for a research misconduct proceeding. The institution, through its designated investigating authority, must—

- a. “Either before or when the institution notifies the respondent of the allegation, inquiry or investigation,
 - (1) promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding,
 - (2) inventory the records and evidence, and
 - (3) sequester them in a secure manner, except that 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;
- b. Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;
- c. Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that 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; and
- d. Maintain the research records and evidence.

Procedures: Preliminary Inquiry and Formal Investigation

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the Director, Office of Research-NSU, shall assess the allegation to determine if: (1) it meets the definition of research misconduct defined above,



and (2) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If the Director, Office of Research-NSU, determines that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted, the Director (or Director's designee) shall complete the preliminary inquiry, including preparation of the inquiry report and giving the respondent a reasonable opportunity to comment on it, within 25 calendar days of its initiation, unless the circumstances warrant a longer period. If the inquiry takes longer than 45 days to complete, the Director, Office of Research-NSU, shall include documentation of the reasons for the delay in the inquiry record. The inquiry report shall contain the following information:

1. The name and position (e.g., faculty rank) of the respondent(s);
2. A description of the allegations of research misconduct;
3. The institutional/intramural and/or extramural grant support involved, including, for example, grant numbers, grant applications, contracts, and publications listing such support;
4. The basis for recommending that the alleged actions warrant an investigation; and,
5. Any comments on the report by the respondent or the complainant.

The Director, Office of Research-NSU, will make a written determination of whether a formal research misconduct investigation is warranted. If the inquiry results in a determination that an investigation is warranted, the Director, Office of Research-NSU shall constitute a Research Misconduct Investigation Committee (RMIC) for the purpose of beginning the investigation within 20 calendar days of that determination. The Chairperson of the RMIC shall assure best efforts to complete the investigation within 60 calendar days from the date on which it began. The Chairperson of the RMIC shall, together with appointed members of the committee, conduct the investigation, prepare the report of findings, provide the draft report for comment to the respondent, and in due course of the investigation timeline submit the final report to the Director, Office of Research-NSU. If it becomes apparent that the investigation cannot be completed the within the designated time frame, the Chairperson shall promptly request an extension in writing from the Director, Office of Research-NSU but shall otherwise to assure completion of the investigation within the newly provided deadline.

In conducting all investigations, NSU institutional authority shall:

- a. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
- b. 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;
- c. 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.

The final investigation report shall:

1. Describe the nature of the allegations of research misconduct;
2. Describe and document any intramural and/or extramural grant support, including identification of grant numbers and listing of grant applications, contracts, and publications that have specified this grant support;
3. Describe the specific allegations of research misconduct considered in the investigation;
4. Identify the institutional policies and procedures under which the investigation was conducted;
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 (A) did occur or (B) did not occur *for each separate allegation* of research misconduct identified during the investigation. If misconduct was found, the RMIC shall (a) identify it as falsification, fabrication, or plagiarism and state whether the identified misconduct was (a.1) intentional, (a.2) knowing, and/or (a.3) in reckless disregard of relevant standards of research integrity; (b) summarize the facts and the analysis supporting the conclusion, considering the merits of any reasonable explanation provided by the respondent as well as any evidence that rebuts the respondent's explanations; (c) identify any publications, based on the research for which a finding of misconduct has been decided, that need correction or retraction; (d) identify the person(s) responsible for the misconduct, and (e) list any current support or known applications or proposals for support that the respondent(s) has pending with NSU, governmental, and/or international institutions or agencies; and
7. Include and consider any comments made by the respondent and complainant on the draft investigation report.
8. The Chairperson of the RMIC shall provide to the Director, OR-NSU, all relevant research records and records of the research misconduct proceedings, including summary results of all interviews, transcripts, or recordings of such interviews. All such documentation shall be archived in the OR-NSU offices with assurance of secured and protected confidentiality of all records archived.



Notice to Respondent: Preliminary Inquiry and/or Formal Investigation

During the research misconduct formal proceedings, the Director, Office of Research or the Chairperson of the RMIC, as noted below, shall provide the following notifications to all identified respondents:

- *Initiation of Inquiry.* Prior to, or at the beginning of, the preliminary inquiry, the Director, Office of Research-NSU, shall provide the respondent(s) written notification of the preliminary inquiry and shall contemporaneously sequester all research records and other evidence needed to conduct the research misconduct inquiry. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.
- *Comment on Inquiry Report.* The Director, Office of Research-NSU, shall provide the respondent(s) an opportunity to respond and comment on the inquiry report in a timely fashion, so that any comments can be attached to the final inquiry report. The respondent(s) should return comments to the Director, Office of Research-NSU, within 20 calendar days
- *Results of the Inquiry.* The Director, Office of Research-NSU, shall notify the respondent(s) of the final results of the inquiry and attach to the notification copies of (a) the inquiry report and (b) the institutional policies and procedures approved by NSU authority for the handling of research misconduct allegations.
- *Initiation of Investigation.* Within a reasonable time after the Director's determination that an investigation is warranted, but not later than 15 calendar days after that determination, the Director shall notify the respondent(s) in writing of the allegations to be investigated by way of formal proceedings. The Director shall give respondent(s) written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the initial inquiry or in the initial notice of the formal investigation.
- *Scheduling of Interview.* The Chairperson of the RMIC shall 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 privately retained legal counsel, if the respondent so wishes.
- *Comment on Draft Investigation Report.* The Chairperson of the RMIC 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, concurrently notifying the respondent(s) that any comments must be submitted within 20 days of the date on which he/she received the draft report. The Chairperson shall ensure that these comments are included and were fairly considered in the *final* investigation report.
- *Appeal.* The final report submitted by the Chairperson of the RMIC to the Director, Office of Research, shall be interpreted as having satisfied due process and having substantiated any and all research misconduct findings. The Director, Office of Research, shall submit to the Vice



Chancellor a final statement of resolution of the investigation with appropriate recommendations for institutional administrative action and sanctions. The Director's final statement shall also specify whether there was indication in the final research misconduct report of violations of civil and/or criminal law. The Vice Chancellor shall issue a final directive as to institutional administrative actions and sanctions issued consequent to findings of research misconduct and the respondent(s) shall be given written notice accordingly. There is no appeal beyond the Vice Chancellor's final directive.