Rowan University
Procedures for Reviewing Alleged Research Misconduct

I. Introduction

A. General Policy

Rowan University is firmly committed to promoting a culture which values the ethical and responsible conduct of research. Accordingly, allegations of research misconduct are taken very seriously, as are the needs to protect the rights of those who make such complaints in good faith and the rights of those who are accused of research misconduct. The policies and procedures described in the following document have been developed to achieve these goals and to comply with Federal regulations and sponsored programs commitments.

The Department of Health and Human Services and the National Science Foundation (NSF) have promulgated regulations and other obligations on Rowan University which define the responsibilities of Public Health Service (PHS) and NSF research grant awardees for dealing with and reporting possible misconduct in research efforts (42CFR, Part 50, Subpart A and 45CFR, Part 689). It should be noted that other federal sources of sponsored programs may impose on the University additional particular procedures for responding to and completing a response to research misconduct allegations (e.g., Department of Defense funding carries its own instructions and procedures on managing a response to research misconduct). Collectively, these federal obligations are referred to below as "Federal obligations" for the sake of brevity.

The Public Health Service Act requires that each agreement for a grant, contract or cooperative arrangement for the conduct of biomedical or behavioral research must have, as part of it, assurances that the institution has established an administrative process to review reports of scientific misconduct in connection with biomedical and behavioral research conducted at or sponsored by the institution. In addition, The National Science Foundation has similar regulations governing the conduct of researchers and scholars supported by NSF grants.

The policy and associated procedures described below will normally be followed when an allegation of possible misconduct is received. Allegations shall be promptly referred to the Research Integrity Officer (see definition below). Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of the institution and its Federal obligations. Any change from normal procedures shall consider the fair treatment of persons alleged to be involved in the alleged misconduct. Any significant variation should be approved in advanced by the Deciding Official (see definition below); such significant variations shall not include minor changes, such as nominal matters, regulatory or Federal obligation related updates, etc. which shall be made by the Research Integrity Officer.

The policy is outlined in detail in the document "Rowan University Policy Governing Research Misconduct."

B. Scope

This statement of policy and procedures is intended to carry out this institution's responsibilities under its Federal Obligations. This document applies to allegations of research misconduct (e.g., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

- A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution;
- Federally supported or other Federal obligations involving, for example, biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for Federal support for biomedical or behavioral research, research training or activities related to that research or research training, (3) research records produced in the course of Federally supported research, research training or activities related to that research or research training, or 4) other scholarship or research involving a Federal obligation. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for Federal funds resulted in a grant, contract, cooperative agreement, or other form of Federal support or obligation, and
- Any allegations of misconduct in any research or scholarship conducted at Rowan University, regardless of funding source, BUT student academic work is specifically excluded from this Procedure and the University's Policy on Research Misconduct.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research or scholarly misconduct that occurred within six years of the date the institution or HHS or other source of Federal obligation received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b) and other relevant regulations.

II. Definitions

Allegation means any written or oral statement or indication of possible scientific, research, or scholarly misconduct made to the Research Integrity Officer.

Complainant means a person who makes an Allegation.

Conflict of interest means the real or apparent interference of one person's interest with the interests of other person, where potential bias may occur due to prior or existing personal or professional relationships, or as otherwise defined by the University.

Deciding Official means the institutional official who makes final determinations on allegations of scientific, research, or scholarly misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and shall have no direct prior involvement in the institution's preliminary assessment, inquiry, investigation, or other proceeding. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. The current Deciding Official is Mei Wei, PhD., Vice President for Research.

Employee means, for the purpose of this policy only, any person paid by, under the control of, or affiliated with the Rowan University, including but not limited to faculty (full-time or otherwise appointed), physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers, so long as they are involved in research or scholarship supported by a Federal obligation.

Good faith allegation means an allegation made with the honest belief that scientific, research, or scholarly misconduct may have occurred. An allegation is not in good faith if it is made intentionally or

knowingly false, or with reckless disregard for or willful ignorance of facts that would disprove the allegation.

Inquiry means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific, research, or scholarly misconduct warrants an investigation.

Institution means Rowan University.

Institutional counsel means legal counsel who represents the institution during the scientific, research, or scholarly misconduct preliminary assessment, inquiry, or investigation and who is responsible for advising the Research Integrity Office and the inquiry and investigation committees and the Deciding Official on relevant legal issues.

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(s), and the seriousness of the misconduct. Investigation may include but is not required to include suggestions for responses, settlement, discipline, or other responses.

ORI means the Office of Research Integrity, the office within the Department of Health and Human Service (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

PHS means the U.S. Public Health Service, an operating component of the DHHS.

PHS regulation means the Public Health Service regulation establishing standards for institutional inquiries - and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."

PHS Support means PHS grants, contracts, or cooperative agreements or applications, therefore.

Research Integrity Officer means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer is Laszlo M. Szabo, Esq., Associate Vice-President and Chief Research Compliance Officer.

Scientific, Research, or Scholarly misconduct is defined in two parts, both of which must be met for a determination of such misconduct to be made:

First, as fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, performing, or reviewing scientific, research or scholarly result, or in reporting such results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or other necessary elements of scholarship or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person’s ideas, processes, or results, or works without giving appropriate credit (self-plagiarism is excluded from this definition)

- Serious deviation from accepted practices includes but is not limited to stealing, destroying, or damaging the research property of others with the intent to alter the research record; and directing or encouraging others to engage in fabrication, falsification or plagiarism. As defined here, it is limited to activity related to the proposing, performing, or reviewing of research, or in the reporting of research results and does not include misconduct that occurs in the research setting but that does not affect the integrity of the research record, such as misallocation of funds, sexual harassment, and discrimination, which are covered by other University policies.

Second, finding of misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly (these apply as well to managing or otherwise supervising research personnel);
    - Intentionally means: To act intentionally means to act with the aim of carrying out the act.
    - Knowingly means: To act knowingly means to act with awareness of the act.
    - Recklessly means: To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

      and
- The allegation be proven by a preponderance of evidence.

Definitions of scientific, research, or scholarly misconduct otherwise defined by Federal obligation shall in their entirety supersede the above definition(s).

The above definitions do not include honest error or honest differences in interpretations or judgments of data. It also does not include authorship disputes. In addition, the institution reserves the right to require adherence to other definitions of misconduct as required by contractual obligations with external sponsors of research.

Research record means any data, document, computer file, 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 an allegation 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. Such records also include any and all relevant scholarly or scientific records used in the course of completing a Federal obligation. The research record shall, to the degree possible, be the original source records used in the course of the work, and it is the affirmative obligation of the respondent, and all involved in the research to provide such original source records. Research records are owned by the Institution as the

recipient of federally sponsored research, and all Institutional members engaged in research (e.g., faculty members) are responsible for securing and maintaining these research records, and do not own the research records.

Respondent means the person(s) against whom an allegation of scientific, research, or scholarly misconduct is directed or the person whose actions are the subject of the preliminary assessment, inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The Deciding Official, or the University President, shall appoint the RIO who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. These responsibilities include, but are not limited to, the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct to determine whether it falls within the definition of research misconduct and warrants further action;
- As necessary, take interim action and notify ORI or other federal sponsors of special circumstances;
- Sequester research data and evidence pertinent to the allegation of research misconduct maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for review, comment, or respond to allegations, evidence, and committee reports;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees; ensure that those committees are properly staffed and that there is expertise appropriate to conduct the required evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct –doing so in a summary manner;

- Notify and make reports to relevant federal sponsors or other entities required through the University's Federal obligations;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to federal sponsors or other entities required under the Institution's Federal obligations.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the Institution. At the discretion of the Research Integrity Officer, and if it would benefit the Institution's Federal obligations, the complainant will be interviewed at the inquiry stage. The complainant must be interviewed during an investigation and be given the transcript or recording of the interview for correction (corrections shall be solely for grammar, spelling, or technical terms). The institution may choose to provide (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. The institution requires that comments on the draft investigation report be submitted within 30 days of the date on which the complainant received the draft report. The institution will consider any relevant comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 or other Federal obligations and the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript (corrections shall be solely for grammar, spelling, or technical terms), and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction (corrections shall be solely for grammar, spelling, or technical terms), and have the corrected recording or transcript included in the record of investigation; and
- Receive 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 be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments

will be considered where relevant by the institution and addressed in the final report.

The respondent will be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct. With the advice of the RIO or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI or other federal sponsors. To the degree permitted under various federal obligations, the respondent will have the opportunity to request an institutional appeal.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO, decide whether an investigation is warranted under Federal obligations. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI or other federal sponsors or entities, together with a copy of the inquiry report meeting the requirements within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI or other federal sponsors or entities may assess the reasons why the institution decided not to conduct an investigation. Once the DO determines that an investigation is warranted, the inquiry is completed.

The DO will receive the investigation report and, after consulting with the RIO, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed actions are provided to ORI or other federal sponsors or entities.

IV. General Policies and Principles

A. Responsibility to Report Research Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at:

Laszlo Szabo, Esq., AVP of Research Compliance and
Chief Research Compliance Officer
South Jersey Technology Park at Rowan University
Division of University Research, Suite 103
107 Gilbreth Parkway
Mullica Hill, NJ 08062
Tel: 856-256-5154
szabolm@rowan.edu

to discuss the suspected research misconduct informally. This may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. Such allegations may also be made anonymously.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an affirmative obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall, as required under Federal obligations: (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. The RIO shall use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. The institution shall provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

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 RIO, 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, and otherwise coordinate with other relevant members of the Institution.

E. Protecting the Respondent

As requested, and as appropriate, the RIO and other institutional officials shall make reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for under Federal obligations and the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice; such counsel, but not the personal advisors, may attend only with the permission of Institution's legal counsel, or as required by law. Such counsel may not, however, participate in any way in any of the proceeding, nor unreasonably alter or delay the proceeding.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS or other Federally supported research processes. In the event of such a threat, the RIO will, in consultation with other institutional officials, such as the DO, and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the

handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI or other federal sponsors, immediately if they have reason to believe that any of the following conditions exist or may reasonably come to exist in the near future:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will promptly assess the allegation to determine whether it is sufficiently credible and specific so that: 1) the potential research misconduct and at least one key person can be identified (e.g., if the respondent is not known, which is unusual, the RIO shall work to either identify a reasonably relevant respondent or dismiss the allegation as incomplete), and 2) that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of PHS or other Federal obligations, an whether the allegation falls within the definition of research misconduct under Federal obligations. An inquiry must promptly be initiated if these criteria are met.

The assessment period is generally brief, preferably concluded within a week unless there are circumstances where additional time is necessary to complete the assessment. In conducting the assessment, the RIO may 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. The RIO shall, on or before the date, on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will promptly initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO shall make a good faith effort to notify the respondent in writing. If the inquiry subsequently identifies additional respondents, they will be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins,

whichever is earlier, the RIO shall take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and 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. The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The Inquiry committee must consist of at least three members. The membership may vary based on the type of inquiry and members may be reused (e.g., same members for the investigation committee or a standing core group of inquiry committee members), or the RIO may engage outside consultants when necessary to evaluate specific allegations. The Inquiry Committee, as well as the Investigation Committee, may have ex-officio members from other Institutional offices (e.g., legal counsel, etc.).

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The RIO may not serve on the committee as a voting member nor as the Chair. The inquiry committee shall consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and includes individuals with the appropriate scientific, research, or scholarly expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. The RIO shall notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest which directly impact the items involved in the allegation. The respondent must submit objections to no more than ten calendar days. The RIO would make the final determination of whether a conflict exists.

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation preliminary assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence (not all evidence is required at this stage, but all reasonable available evidence or that may become reasonably relevant and available in the course of the inquiry), including the testimony of the respondent, complainant, and key witnesses, as relevant, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of a Federal obligation; and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and Federal

obligations.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO, subsequent to this first meeting, may revise the charges for clarity or to support the resolution of the allegation. The RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee may interview the complainant and shall interview the respondent, and key witnesses or others who are involved in the work, as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and Federal obligations. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of scientific, research, or scholarly misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI or the federal sponsor or entity to determine the next steps that should be taken.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within sixty calendar days of initiation of the inquiry, unless the RIO determines that circumstances reasonably warrant a longer period. If the RIO approves an extension, the inquiry record will include documentation of the reasons for exceeding the 60-day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report will be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of misconduct; (3) the PHS or other Federal obligation source of support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.

Institutional counsel shall review the report for legal sufficiency. Modifications will be made as appropriate in consultation with the RIO and the inquiry committee. The inquiry report will include: a summary of the inquiry process used if different from this Procedure; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 calendar days of the finalized date of the

inquiry report, and include provide a copy or reference to the institution's policies and procedures on research misconduct and relevant Federal obligations (e.g., ORI regulations).

Any relevant comments that are submitted by the respondent will be attached to the final inquiry report. Based on those comments, the inquiry committee may revise the draft report as it determines to be relevant and appropriate and prepare it in final form. The committee will deliver the final report to the RIO, who shall provide it to the DO as described under this Procedure.

C. Notification to Complainant and Opportunity to Comment

Solely at the discretion of the RIO or other institutional officials, the institution may provide the complainant with a copy of the draft inquiry committee report, or relevant portions of it, for comment. If the RIO chooses this option, the complainant's reasonably relevant comments must be submitted within 10 calendar days of the date on which they received the draft report and those comments may be included and considered in the final report.

D. Institutional Decision and Notification

1. Decision by Deciding Official

The RIO will timely transmit the final inquiry report and any comments to the DO, in writing and inform the DO the recommendation of the Inquiry committee to conduct an investigation or not. The DO will timely determine whether the investigation is warranted.

2. Notification to ORI

Within thirty calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI or other federal sponsors or entities with the DO's written decision and a copy of the full inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO will provide the following information to ORI upon request: (1) the 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 to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents will be provided to ORI or other authorized HHS.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation will begin within thirty calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to determine whether research misconduct took place –this is completed by developing a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation must also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it

affects research that forms the basis for public policy, clinical practice, or public health practice. Under Federal obligations the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO shall: (1) notify the ORI Director or relevant federal sponsors of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO will also give the respondent timely written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation. Such new allegations be incorporated into the investigation, and do not require their own preliminary assessment nor inquiry.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceedings that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The investigation committee may consist of three members. The membership may vary based on the type of inquiry and members may be reused (e.g., from the inquiry committee) or the RIO may engage outside consultants or experts when necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution. The investigation committee may have ex-officio members from other Institutional offices (e.g., legal counsel, etc.).

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The RIO shall not be a voting member nor the Chair of the committee. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant, and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. The RIO will notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest which directly impact the items involved in the allegation. The respondent must submit objections to no more than ten calendar days. The RIO will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee
   The RIO will define the subject matter of the investigation in a written charge to the committee that:
   - Describes the relevant allegations and related issues identified during the inquiry;
   - Identifies the respondent and other key individuals;

- Informs the committee that it must conduct the investigation as prescribed under the Institution's Policy, this Procedure, and Federal obligations;
- Defines research misconduct and what may not be research misconduct;
- Informs the committee that it must evaluate the relevant evidence and relevant testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible; and, with the assistance of legal counsel, provide a description of the preponderance of evidence standard.
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that by a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly (including management or supervision); and
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and Federal obligations.

2. First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures and sources of Federal obligations. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO shall:

- Use reasonably diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all relevant research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each respondent, complainant in required, 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 to the degree required record or transcribe each interview, provide the recording or transcript to the interviewee for correction (corrections shall be solely for grammar, spelling, or technical terms), and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 days from the first meeting of the Investigation Committee, including conducting the investigation, preparing the report of findings, providing the draft

report for comment and sending the final report to ORI or the relevant federal sponsor or entity; the investigation may be completed in a period other than 120 days if required by a Federal obligation. However, if the RIO determines that the investigation cannot be completed within this 120-day period or other Federally obligated period (which is not uncommon), they will submit to that federal sponsor or entity a written request for an extension, setting forth the reasons.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee, with the support of the RIO for regulatory and administrative aspects, are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent (e.g., The respondent's CV or resume may be included as part of the identification.)
- Describes and documents the PHS or other federally obligated support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS or other federal support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI or other Federal obligations previously;
- Identifies and summarizes the relevant research records and relevant evidence reviewed and identifies any evidence taken into custody but not reviewed; and also identifies any records or evidence that was not obtained and the reasons for that inability (e.g., unresponsive witness or respondent, destroyed data, etc.); and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS or Federal obligation support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies or other federal sponsors or entities.

B. Comments on the Draft Report and Access to Evidence

1. **Respondent**

   The RIO will give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. **Complainant**

   To the degree required by Federal obligations, the Institution may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If the RIO chooses

this option, the complainant's comments must be submitted within 30 days of the date on which they received the draft report and the relevant comments must be included and considered in the final report.

3. **Confidentiality**
   In distributing the draft report, or portions thereof, to the respondent, and if relevant the Complainant, the RIO will inform the recipient of the confidentiality requirements under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality (e.g., a non-disclosure agreement).

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, such assistance limited to regulatory or administrative support, including ensuring that the respondent's and on case by case complainants comments are included and reasonably considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct (which may include suggested responses, changes to research policy or procedure, or discipline). If this determination significantly varies from the findings of the investigation committee (e.g., includes additional suggestions for discipline), the DO will, as part of their written determination, explain the basis for rendering a decision different from the findings of the investigation committee. In such cases, the DO's additional findings will be provided for legal review prior to adoption by the DO. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis, but in such an instance, must specifically describe the basis and goals for further fact-finding and analysis.

When a final decision on the case has been reached, the RIO will notify the respondent, and if required the complainant, in writing. That notification need not provide the details or full resolution or decision about the research misconduct. After informing ORI or the federal sponsor, the DO, in consultation with legal counsel and other Institutional leadership, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

Appeal of the committee's decision may be made to the President of Rowan University who may decline in their sole discretion for any or no reason (except where an appeal is of right under a specific Federal obligation) or may agree to hear the appeal. The appeal may result in upholding or reversal or modification of the Institution's finding on research misconduct, or a decision to not pursue further steps beyond the finding. The appeal must be completed within 60 days of filing unless the institution has secured an extension from the ORI or other federal sponsor. After the President has made a final decision, the RIO will inform the Respondent.

E. Notice to ORI or Other Federal Sponsors of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day or other Federally obligated period for completion of any appeal, submit the following to ORI or the federal sponsor: (1) a copy of

the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent; and other information as required under Federal obligations.

F. Maintaining Records for Review by ORI

The RIO will maintain and provide to ORI or other federal sponsors upon request "records of research misconduct proceedings" as that term is defined by Federal obligations. Unless custody has been transferred to HHS or ORI or another federal sponsor has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any proceeding involving the research misconduct allegation (the records do not need to be maintained on-site by the Institution). The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or other federal sponsors to conduct its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued to the degree required by law. The RIO must notify federal sponsors in advance if there are plans to close a case at the inquiry (if permitted), investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to the federal sponsor.

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO, and other relevant offices at the Institution (e.g., legal counsel, faculty affairs, etc.). The administrative actions may include:

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

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under its Federal obligations.

If the respondent, without admitting to the misconduct, elects to resign their position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps to the degree required under Federal obligations. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence, and if permitted or required by Federal obligations, to make adverse findings or presumptions based on such non-cooperation.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI or federal sponsor concurrence where required by Federal obligations, the Institution will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the Institution may consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reasonable references to the research misconduct allegation from the respondent's personnel file.

C. Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the Institution, through the RIO, must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO and legal counsel, and with the complainant if required, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps DO approve.

D. Allegations Not Made in Good Faith

If relevant, the DO, in consultation with the RIO and legal counsel, will determine whether the complainant’s allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, then the DO will determine whether any administrative or other action should be taken against the person who failed to act in good faith.

References

42 CFR § 93 et seq.

45 CFR § 689 et seq.

NSF Dear Colleague Letter, February 6, 2023

Modified Version 1: 4-11-2014
Modified Version 2: 1-5-2017
Modified Version 3: 09-16-2021
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