SUNY DOWNSTATE MEDICAL CENTER

POLICY AND PROCEDURE

Subject: RESEARCH MISCONDUCT	**No.** ORA 111414-6
Approved by: Heidi Aronin **Institutional Official**	**Supersedes:** March 23, 2015 **Effective Date:** July 1, 2018

1. PURPOSE

The purpose of this document is to inform SUNY Downstate Medical Center (DMC) faculty, staff, and students engaged in research activities (funded or unfunded) using DMC facilities, the facilities of another institution, or any other off-campus site of DMC's that policy and procedures related to research misconduct apply to their activities.

DMC is committed to excellence in all research endeavors. Individuals will adhere to the highest professional standards of scientific integrity in proposing, performing, reviewing, or in reporting results, of research activities conducted under the auspices of DMC. All faculty, staff, and students shall report observed, suspected or apparent research misconduct, and will cooperate with the DMC officials in the review of allegations and the conduct of inquiries and investigations. All parties have an obligation to provide evidence relevant to research misconduct allegations to institutional officials.

The Institutional Official (IO) has primary responsibility for research conducted under the auspices of DMC. In doing so, the IO may delegate some responsibilities to a designee, and /or work in conjunction with, the Office of Compliance and Audit Services (OCAS).

DMC will thoroughly examine, in a fair and timely manner, all allegations brought forward by a complainant, acting in good faith, in which it is believed that an individual or individuals (hereafter referred to as the respondent[s]) have committed research misconduct.

2. POLICY

This policy establishes DMC's responsibilities in responding to research misconduct issues and our commitment to maintaining the integrity of our research endeavors. The guidelines provided in this policy are derived from the National Institutes of Health Intramural Research Program Policies & Procedures For Research Misconduct Proceedings and are pursuant to the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.

3. DEFINITIONS

Allegation: A disclosure of possible research misconduct through any means of communication (e.g. by written or oral statement) to an institutional or Health and Human Services (HHS) official.

Charge Letter: A written notice, as well as any amendments to the notice that are sent to the respondent stating the findings of research misconduct and any administrative actions.

Complainant: A person who, in good faith, makes an allegation of research misconduct.

Compliance Officer: The campus official responsible for compliance.

Deciding Official: The Campus President is the Deciding Official (DO).

Evidence: Any document, tangible item or testimony offered or obtained during research misconduct proceedings that tends to prove or disprove the existence of an alleged fact.

Inquiry: The process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an Investigation.

Institutional Official: The Institutional Official is responsible for handling allegations of scientific misconduct involving biomedical or behavioral research or research training.

Investigation: The formal development of a factual record and the examination of that record leading to a decision not to make a finding or research misconduct or to a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions.

Preponderance of the Evidence: Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Public Health Service (PHS): The unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

PHS Support: PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

Research: A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) 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.

Research Misconduct: The fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication – making up data or results and recording or reporting them.
- Falsification – manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism – the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct made under this Policy requires that: (a) there be a significant departure from accepted practices of the relevant research community; and (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence.

Research Record: 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 a DMC official by a respondent in the course of the research misconduct proceeding.

Respondent: The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

4. GENERAL PROCEDURES

4.1 Allegations of Research Misconduct: Allegations of research misconduct may be presented verbally or in writing by the complainant to the Institutional Official (IO) or to OCAS. The complainant is responsible for making allegations in good faith, and maintaining confidentiality. The complainant must cooperate at all phases of the research misconduct process, including an assessment, an inquiry and an investigation if required. If anonymity is requested, the IO and/ or OCAS will make a best effort to maintain such anonymity throughout the process, as possible.

An anonymous report may also be submitted through DMC's Compliance Line. Reports can be communicated via telephone at 1-877-349-SUNY (7869) or submitted via the web. Click on the "Compliance Line" link on the main Downstate web-page: www.downstate.edu.

4.2 Confidentiality: Disclosure of the identity of respondents and complainants shall be limited to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and 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.

4.3 Protecting Respondents, Complainants, Witnesses, and Committee Members: DMC workforce members may not retaliate in any way against respondents, complainants, witnesses, or Inquiry/Investigation committee members. DMC workforce members should

immediately report any alleged or apparent retaliation against these parties to the IO or OCAS, who will review the matter and, where appropriate, refer the matter to applicable DMC officials.

4.4 Ensuring Fair Assessment/Inquiry/Investigation: DMC will take reasonable steps to ensure an impartial unbiased process to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the process.

4.5 Assessment: Upon receiving an allegation of research misconduct, the IO/Designee and/or OCAS may interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

5. INQUIRY PROCEDURES

5.1 Purpose of the Inquiry: Once it is determined that the criteria[1] for an inquiry are met, the IO/Designee initiates the inquiry process. The purpose of the inquiry is to determine whether the allegation or apparent instance of research misconduct warrants an investigation based on an initial review of the available evidence. The purpose of the inquiry is not to make a final determination based on the merits of the allegation.

5.2 Timeframe: The inquiry committee is generally convened within 30 days of the determination to convene an inquiry. The inquiry, including the final report and decision of whether an investigation is warranted, should generally be completed within 60 days of the convening of the inquiry.

5.3 Sequestration: Once the determination is made to convene an inquiry, the IO/Designee will take all reasonable and practicable steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding. Research records include any data, document, email, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research. The IO/Designee will work to sequester records in a manner which will cause as minimal disruption to research as possible. A documented inventory of the sequestered records and evidence will be inventoried and secured.

5.4 Respondent Notification of Inquiry: Within 15 business days of the determination to convene an inquiry, the IO/Designee notifies the respondent in writing of the allegation(s). Respondent notification includes:

- The specific allegation(s);
- The rights and responsibilities of the respondent;
- The role of the Inquiry committee;
- A description of the inquiry process; and

[1] An inquiry is warranted pursuant to 42 C.F.R. Part 93 if the allegation 1) Falls within the definition of research misconduct, 2) falls within the applicability guidelines established at 93.102 and 3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

- Copy of DMC's Research Misconduct Policy & Procedure.

5.5 Dean/Department Chair Notification of Inquiry: The Dean and Department Chair, or equivalent in the respondent's department, are also notified in writing by the IO/Designee of the determination to convene an inquiry.

5.6 Composition of the Inquiry Committee: The IO, in consultation with the DO, will appoint faculty members to serve on the Inquiry committee and designate one faculty member as the chair. The Inquiry committee includes at least three members meeting the following criteria:

- Have appropriate scientific expertise to evaluate the evidence and issues related to the allegation; and
- Have no personal, professional, or financial conflicts of interest with the complainant or respondent.

5.7 Respondent Notification of Inquiry Committee Members: IO/Designee notifies the respondent in writing of the proposed inquiry committee membership. The respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The respondent will submit any objections within seven days of notification of the potential committee membership. The IO makes the final determination of whether any such conflict exists.

5.8 Responsibilities of Inquiry Committee: The Inquiry committee is responsible for determining whether the allegation or apparent instance of research misconduct warrants an investigation based on an initial review of the available evidence. The Inquiry committee may also identify, in the course of its duties, if there are issues which would justify broadening the scope of the misconduct proceeding beyond the initial allegation. The Inquiry committee is not responsible for making a final determination based on the merits of the allegation. The Inquiry committee has access to evidence and documentation relative to the allegation of research misconduct and may request to interview the complainant, respondent, and/or others, if necessary and appropriate. The Inquiry committee comes to a determination of whether an investigation is warranted based on its initial review of the available evidence. The Inquiry committee summarizes its findings and recommendations in a written report to the IO. The inquiry, including the final report and decision of whether an investigation is warranted, should generally be completed within 60 days of the convening of the inquiry. If the inquiry report takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

5.9 Charge to the Inquiry Committee: The IO/Designee provides the charge to the inquiry committee, which includes:

- Purpose of the inquiry;
- Definition of research misconduct;
- Obligation of confidentiality;
- Timeframe for completion;
- Identification of respondent;
- Specific allegation(s) to be evaluated.

Responsibilities of the Inquiry committee, including:

- Review of DMC's Research Misconduct Policy and Procedure;
- Initial review of evidence, including review of documentation and evidence;
- Interviews of complainant, respondent and/or others if deemed necessary and appropriate; and
- Preparation of a final report.

5.10 The Draft Inquiry Report: At the conclusion of an inquiry, the Inquiry committee prepares a written report of its findings and recommendations. The required elements of the Inquiry committee report include:

- Names of Inquiry committee members;
- Committee charge, i.e. the identification of respondent and a description of allegation(s);
- Process used, i.e. DMC's Research Misconduct Policy and Procedure;
- Inventory of evidence reviewed;
- The basis for the Inquiry committee's recommendations for each allegation;
- Identification of any federal support; and
- Any comments on the draft Inquiry committee report by the respondent.

5.11 Respondent's Review of the Draft Inquiry Report: The respondent has the opportunity to review and provide written comments in response to the draft Inquiry committee report. The IO/Designee will forward the draft Inquiry report and attachments to the respondent. The respondent must provide any written comments within 15 days of receipt of the draft Inquiry committee report. The Inquiry committee considers the comments of the respondent, may revise the Inquiry committee draft report, as appropriate, and prepares its final report. Any written comments provided by the respondent must be attached to the final Inquiry committee report. The final Inquiry committee report with all attachments is submitted to the IO/Designee.

The IO/Designee will transmit the final Inquiry report and any comments from respondent to the DO, who will determine in writing whether an investigation is warranted. The Inquiry is completed when the DO makes this determination.

5.12 DO Determination: If the Inquiry committee finds that the allegation meets the definition of research misconduct as defined in DMC's Research Misconduct Policy and Procedure and warrants further action, and the DO concurs, the IO/Designee will formally convene the research misconduct investigation.

If the Inquiry committee finds that the allegation does not meet DMC's definition of research misconduct and/or does not warrant further action, and the DO concurs, the IO formally dismisses the allegation. If requested, the institution will make all practical, reasonable, and appropriate efforts to restore the reputation of the individual alleged to have engaged in research misconduct, but against whom no basis for allegations of research misconduct were found.

5.13 Respondent Notification of Inquiry Determination: The IO/Designee notifies the respondent in writing of the results of the inquiry, including a copy of the final Inquiry committee report with all attachments.

5.14 Dean/Department Chair Notification of Inquiry Determination: The IO/Designee will notify the Dean and Department Chair or equivalent in the respondent's department of the results of the inquiry.

5.15 Federal Oversight Agencies Notification of Determination to Open an Investigation: When applicable, the IO/Designee notifies the appropriate federal agencies, i.e., Office of Research Integrity (ORI) in writing of any decision to open an investigation within 30 days of the determination that an investigation is warranted. This written communication includes a copy of the Inquiry committee report and other information and references as required by federal oversight agencies.

5.16 Complainant Notification of Inquiry Determination: The IO/Designee will notify the complainant of the determination of the inquiry.

6. INVESTIGATION PROCEDURES

6.1 Purpose of Investigation: Once DMC determines that the criteria for an investigation have been met, the IO/Designee initiates the investigation process. The purpose of the investigation is to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the research misconduct.

6.2 Timeframe: The Investigation committee is generally convened within 30 days of the determination to convene an investigation. The investigation, including the final report and findings for each allegation, should generally be completed within 120 days of the convening of the investigation. However, if the IO/Designee determines that the investigation will not be completed within this 120 day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The IO/Designee will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

6.3 Sequestration: The IO/Designee will take all reasonable or 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.

6.4 Respondent Notification of Investigation: Within 15 days of the determination to convene an investigation, IO/Designee notifies the respondent in writing of the decision to convene an investigation. Respondent notification includes:

- The specific allegation(s);
- The rights and responsibilities of the respondent;
- The role of the investigation committee;
- The investigation process and expected timeline; and
- Copies of DMC's Research Misconduct Policy and Procedures.

6.5 Dean/Department Chair Notification of Investigation: The Dean and Department Chair, or equivalent, in the respondent's department are also notified in writing by the IO/Designee of the determination to convene an investigation.

6.6 Federal Oversight Agencies Notification of the Opening on an Investigation: As stated above in §5.15, the IO/Designee notifies the appropriate federal agencies (i.e., ORI) in writing of any decision to open an investigation within 30 days of the determination that an investigation is warranted. This written communication includes a copy of the Inquiry committee report and other information and references as required by federal oversight agencies.

6.7 Appointment of the Investigation Committee: The IO/Designee, in consultation with the DO, will appoint an Investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The Investigation committee will consist of individuals who have the professional time, resources and appropriate scientific expertise to evaluate the evidence and issues related to the allegation. Selected individuals on the Investigation Committee cannot have any conflict of interest with those involved with the investigation. Individuals appointed to the Investigation committee may also have served on the Inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, DMC may select committee members from outside the institution.

6.8 Respondent Notification of Committee Membership: The respondent will be notified, in writing, of the proposed investigation committee membership. The respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The respondent will submit any objections within seven business days of notification of the potential committee membership. The IO/Designee makes the final determination of whether any such conflict exists.

6.9 Responsibilities of Investigation Committee: The Investigation committee led by the committee chair is responsible for conducting a thorough examination of all facts and evidence relevant to the investigation to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the research misconduct. The Investigation committee may also identify, in the course of its duties, if there are issues which would justify broadening the scope of the misconduct proceeding beyond the initial allegation. The Investigation committee must interview the complainant, the respondent, and any other available persons who have been reasonably identified as having information relevant to the investigation. Interviews are recorded or transcribed and provided to the interviewee for correction.

The Investigation committee comes to a finding for each allegation, determining whether research misconduct occurred, by whom and to what extent, taking into account that a finding of research misconduct requires:

- A preponderance of evidence;
- A significant departure from accepted practices in the relevant scientific community; and
- That the research misconduct must have been committed intentionally, knowingly or recklessly.

The Investigation committee summarizes its findings and recommendations in a written report to the DO. The investigation, including the final report and findings for each allegation, should generally be completed within 90 days of the convening of the investigation.

6.10 Charge to the Investigation Committee: The committee chair provides the charge to the investigation committee, which includes:

- Purpose of the investigation;
- Definition of research misconduct;
- Requirements for findings of research misconduct;
- Obligation of confidentiality;
- Timeframe for completion;
- Identification of respondent;
- Specific allegation(s) to be evaluated;
- Responsibilities of the investigation committee, including:

  - Review of DMC's Research Misconduct Policy and Procedure;
  - Examination of evidence, including review of all relevant documentation;
  - Interviews of complainant and respondent;
  - Interviews of other persons as necessary and appropriate;
  - A finding, for each allegation, determining whether research misconduct occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct; and
  - Preparation of a final report.

6.11 Draft Investigation Report: At the conclusion of an investigation, the Investigation committee prepares a written report that summarizes its findings and recommendations. The required elements of the Investigation committee report include:

- Names of investigation committee members;
- Committee charge, i.e. the identification of respondent and a description of allegations;
- PHS support related to the alleged misconduct, including grant numbers, grant applications, contracts, and publications listing PHS support where applicable;
- Process used, i.e. DMC's Research Misconduct Policy and Procedure;
- Inventory of evidence reviewed;
- A finding as to whether research misconduct occurred for each separate allegation identified during the investigation, and whether it was committed intentionally, knowingly, or recklessly;
- Identification of each finding of research misconduct as plagiarism, falsification, fabrication, or other serious deviation from accepted practices;
- Identification of the individual responsible for each finding of research misconduct;
- Summary of the facts and analysis supporting the conclusion;
- Identification of any additional federal support or known applications or proposals for support that the respondent has pending;
- Identification of any publications that require correction or retraction; and
- Any comments on the draft Investigation committee report by the respondent.

6.12 Respondent's Review of the Draft Investigation Report: The respondent has the opportunity to review and provide written comments in response to the draft Investigation committee report. The IO/Designee will forward the draft Investigation committee report and attachments to the respondent. If the respondent requests access to evidence and documentation supporting the decision of the investigation committee, the respondent may have supervised access to such evidence and documentation. The respondent must provide any written comments within 30 days of receipt of the draft Investigation committee report. The Investigation committee, after consideration of the comments of the respondent, may revise the Investigation committee draft report as appropriate, and prepare its final report. Recordings or transcripts from all interviews must be attached to the final Investigation committee report. Any written comments provided by the respondent must be attached to the final Investigation committee report. The final Investigation committee report with all attachments is submitted to the IO/Designee.

The IO/Designee will transmit the final Investigation report and any comments from respondent to the DO who makes the final determination.

6.13 DO Determination: If the Investigation committee finds that research misconduct has occurred, and the DO concurs, the DO in consultation with institutional officials, will determine an appropriate course of disciplinary action in accordance with regulatory standards and established SUNY DMC policies/procedures.

If the Investigation committee determines that research misconduct has not occurred, and the DO concurs, then the matter is closed. If requested, the institution will make all practical, reasonable, and appropriate efforts to restore the reputation of the individual alleged to have engaged in research misconduct, but against whom no findings of research misconduct were found.

6.14 Respondent Notification of Investigation Determination: The IO/Designee notifies the respondent in writing of the final investigation determination, including a copy of the final Investigation committee report with all attachments.

6.15 Dean/Department Chair Notification of Investigation Determination: The Dean and Department Chair, or equivalent, in the respondent's department are also notified in writing by the IO/Designee of the investigation determination.

6.16 Federal Oversight Agencies Notification of the Investigation Determination: As required, the IO/Designee notifies federal oversight agencies, i.e., ORI, in writing of the Investigation committee's findings, whether the institution accepts the investigation committee's findings, the final accepted institutional findings, and any completed or pending institutional actions or sanctions. This notification includes a copy of the Investigation report with all attachments.

6.17 Complainant Notification of the Investigation Determination: The IO/Designee will notify the complainant of the determination of the investigation.

7. COMPLETING THE RESEARCH MISCONDUCT PROCESS

7.1 Employment Separation: The separation of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, shall not preclude or terminate the research misconduct proceeding. If the respondent, without admitting to the misconduct, elects to resign his or her 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. If the respondent refuses to participate in the process after resignation, the IO/Designee 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.

7.2 Closing a Case at the Inquiry or Investigation Stage: In the event that a respondent has admitted guilt during the inquiry or investigation stage, the Inquiry/Investigation committee must follow and complete all procedures described above (Inquiry) §5.10 – §5.16, (Investigation) §6.11 – §6.17.

8. NOTIFICATION OF SPECIAL CIRCUMSTANCES

8.1 Interim Administrative Actions and Notifying ORI where Public Health Service funds are involved: Throughout the research misconduct proceeding, the IO/Designee 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 supported research process. In the event of such a threat, the IO/Designee will, in consultation with the DO and legal counsel, take appropriate interim action to protect against any such threat. The IO/Designee must, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- 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, (or, in the case of NSF funds, of others potentially affected);
- 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.

9. RESEARCH MISCONDUCT PROCEEDING RECORDS PROCEDURES

9.1 Retention: All documentation and records related to allegations of research misconduct, regardless of whether they resulted in an inquiry or investigation will be retained and secured by IO/Designee for a period of seven years from the date of the completion of the research misconduct proceedings.

10. ASSURANCE PROGRAM – ANNUAL REPORTING

10.1 Annual Report on Possible Research Misconduct: On an annual basis the DMC IO/Designee will submit an Annual Report on Possible Research Misconduct (PHS form 6349, Appendix J) to ORI (42 C.F.R. § 50.103(b)). ORI mails this form to institutions in January of each year and institutions must respond by the designated deadline, usually in March/April.

ATTACHMENTS: DMC Inquiry/Investigation Report Template

REFERENCES: National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings; Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. Part 93.