



POLICIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Dated: June 15, 2023

Supersedes: NYMC Research Misconduct Policy dated October 13, 2004

Last Review: June 15, 2023

I. PURPOSE

To provide an appropriate policy and related procedures regarding the investigating and reporting of possible Research Misconduct, as defined herein, and to ensure compliance, when applicable, with institutional responsibilities under the Public Health Service (“**PHS**”) Policies on Research Misconduct regulations at 42 CFR Part 93, which apply to allegations of Research Misconduct and Research Misconduct involving PHS supported research, research training programs, and research and research training-related activities, as well as applications or proposals for PHS support for the same (collectively, “**PHS Supported Research**”).

II. POLICY

It is the goal of the New York Medical College (“**NYMC**” or the “**College**”) to recognize when Research Misconduct undermines the integrity of the scientific process and the research enterprise. This policy was developed to prevent, detect, and address Research Misconduct in NYMC research programs.

In all scientific and research activities, NYMC expects the individuals performing research to observe the highest standards of honesty and professional conduct. It is integral for the enterprise of scientific and medical research to maintain the trust and confidence of both the scientific community and the public at large in the integrity of the scientific process. Unethical behavior represents a breach of confidence among scientists and researchers. It also undermines the confidence of the public and research subjects in the reliability of science and medicine. For these reasons, NYMC considers Research Misconduct to be a betrayal of fundamental academic, medical, and scientific principles and shall promptly deal with all instances of possible research misconduct according to the procedures set forth in this policy.

III. SCOPE

This policy applies to all research, research training, or activities related to research or research training conducted under the auspices of NYMC, regardless of the source of funding for the research, and to any person paid by, under the control of, or affiliated with NYMC, including individuals who held such positions at the time of the alleged Research Misconduct.

This policy and associated procedures will be followed by NYMC upon receipt of an allegation of possible Research Misconduct. Allegations of Research Misconduct may arise in connection with the proposal, conduct, review, or reporting of research, including any Research Record (as defined below) generated from that research. Allegations may be disclosed through any means of communication, including written or oral statement or other communication. When applying this policy to allegations of Research Misconduct involving non-PHS Supported Research, NYMC may, to the extent not prohibited by law, and where circumstances clearly warrant, and with the prior approval of the Office of General Counsel and notice to the Respondent, waive or deviate from specific policy requirements.

Allegations brought more than six (6) years after the alleged Research Misconduct occurred will not normally be investigated, unless there is a compelling reason to do so, such as when circumstances indicate that the alleged Research Misconduct was not reasonably discoverable at an earlier time. This six (6) year limit does not apply for PHS Supported Research where (i) the Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six (6) year limitation through the citation, republication, or other use for the potential benefit of the Respondent of the Research Record that is alleged to have been Fabricated, Falsified, or Plagiarized (as defined below); or (ii) ORI (as defined below) or NYMC, following consultation with ORI, determines that the alleged Research Misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

IV. DEFINITIONS

Complainant means a person or entity who in Good Faith makes an allegation of Research Misconduct. A number of different sources may serve as a Complainant, including a party outside of NYMC, a journal, or ORI.

Conflict of Interest means unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or witnesses.

Deciding Official means the College Official who makes final findings on Research Misconduct proceedings and any responsive NYMC actions. At NYMC, the Deciding Official is the Dean of the School of Medicine or the School of Health Sciences and Practice, as appropriate (the “Dean”). The Dean of the School of Medicine, in his or her discretion, may delegate this responsibility to the Dean of the Graduate School of Biomedical Sciences. If the Dean is unable to serve as Deciding Official for any reason, the CEO will act as Deciding Official. If the CEO is unable to act as Deciding Official, the President or the President’s designee will act as Deciding Official.

Good Faith as applied to a Complainant or witness means having a belief in the truth of one’s allegations or testimony that a reasonable person in the same position could have based on the information known to the person at the time. Good Faith as applied to a member of the Inquiry Committee or investigation committee (“**Investigation Committee**”) means cooperating with the Research Misconduct Proceeding by carrying out the duties assigned impartially for the purpose of helping NYMC meet its responsibilities under this policy.

HHS means the U.S. Department of Health and Human Services.

Inquiry means gathering information and initial fact-finding to determine whether an allegation or apparent instance of Research Misconduct warrants an Investigation.

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

College Official means an institutional member with the authority and responsibility to respond to and/or report allegations of Research Misconduct. Such officials include the Research Integrity Officer, members of the General Counsel's office, and other management-level employees.

Notice generally means a written communication served in person, sent by mail or its equivalent to the last known street address of the addressee, or sent electronically to the last known email address of the addressee.

ORI means the Office of Research Integrity, the office within HHS that is responsible for addressing research integrity and misconduct issues related to PHS Supported Research.

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

Research Integrity Officer ("RIO") means a senior official appointed by NYMC to implement this policy, assess allegations, and manage the Inquiry and Investigation process. At NYMC, the RIO is the Vice President for Research. If the Vice President for Research is unable to serve as RIO for any reason, the Chancellor and CEO will designate an acting RIO.

Research Misconduct means Fabrication, Falsification, or Plagiarism in proposing, performing, reviewing, or reporting research results. The following definitions apply:

1. **Fabrication** is making up data or results and recording or reporting them.
2. **Falsification** is 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.
3. **Plagiarism** is appropriating another person's ideas, processes, results, or words, without giving appropriate credit. It includes the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. Plagiarism does not include authorship or credit disputes.

NYMC has the burden of proof for making a finding of Research Misconduct by a Preponderance of the Evidence. NYMC may consider the destruction, absence of, or Respondent's failure to provide research records as evidence of Research Misconduct if it proves the Respondent intentionally, knowingly, or recklessly destroyed them, failed to maintain them in a departure from relevant standards, or otherwise failed to produce them (42 CFR § 93.106(b)).

Honest error or differences of opinion do not constitute Research Misconduct. The Respondent has the burden to demonstrate honest error or difference of opinion as an affirmative defense by a Preponderance of the Evidence (42 CFR § 93.106(b)). NYMC, through the Investigation Committee, will also consider evidence of honest error or difference of opinion to the extent relevant in evaluating whether misconduct was committed intentionally, knowingly, or recklessly.

A finding of Research Misconduct requires that the Institution determine that:

1. There is a significant departure from accepted practices of the relevant research community;
2. The misconduct is committed intentionally, knowingly, or recklessly; and
3. The allegation is proven by a Preponderance of the Evidence.

Research Misconduct Proceedings means any actions related to alleged Research Misconduct taken under this policy, including but not limited to allegation assessments, Inquiries, and Investigations.

Research Record means (i) 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 (ii) any documents and materials provided to funding agencies or an institutional official by a Respondent in the course of the Research Misconduct Proceedings.

Respondent means the person against whom an allegation of Research Misconduct is directed or the person whose actions are the subject of the Inquiry or Investigation. There can be more than one Respondent in any Inquiry or Investigation.

Retaliation means an adverse action taken against a Complainant, witness or Committee member by a College Official or an employee in response to a Good Faith allegation or Good Faith cooperation with a Research Misconduct Proceeding.

V. GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct and Cooperate During Proceedings

Employees or individuals associated with NYMC who believe in Good Faith that an act of Research of Misconduct has occurred or is occurring have an obligation to report such suspected Research Misconduct to the RIO, or to any individual listed below, who is then required to immediately direct the allegation to the RIO:

- a. A Department Chairperson;
- b. The Dean; or
- c. Legal/Compliance.

All members of the NYMC community have an obligation to provide relevant evidence regarding allegations. NYMC employees are required, as a condition of their employment or affiliation, to cooperate with the RIO and other College Officials in the review of allegations and participate in these procedures, including providing all relevant documents and data, attending meetings, and answering questions put to them, upon reasonable notice. If others subject to this policy, for example guest researchers, refuse to cooperate with these procedures, NYMC will disassociate itself from their research; revoke all College support and/or approval; and report to government authorities, as required and applicable.

B. Problematic Conduct that Does not Qualify as Research Misconduct

The RIO will evaluate each allegation to assess whether the alleged conduct is within the scope of this policy. If the RIO determines the alleged conduct does not constitute Research Misconduct but involves other problematic conduct, the allegation may be referred to the appropriate College Official or committee for further investigation (*e.g.*, an IRB, Privacy Officer, or Director of Human Resources). Outside consultants may also be engaged to assist with such matters, at NYMC's discretion. On a case-by-case basis, NYMC also reserves the right to employ the procedures in this policy to address problematic conduct that does not qualify as Research Misconduct.

Examples of problematic conduct that may not rise to the level of Research Misconduct, but may warrant referral by the RIO, include but are not limited to:

1. Intentional or reckless disregard of, or significant and substantial departure from accepted research practices, applicable federal regulations, College policies, IRB directives on the appropriate and ethical conduct of human research, or recognized research ethics;
2. The submission of research forms or documents required by study sponsors, which do not constitute Research Records, that contain intentional or reckless material misstatement or omissions;

3. Misuse of research funding or violation of the terms of the funding agreement; or
4. Falsification of academic or professional credentials.

C. Role of IRB and/or IACUC in Problematic Conduct Involving Research with Human and/or Animal Subjects

If an allegation of Research Misconduct implicates human and/or animal subjects research, the RIO should consult with NYMC's Office of General Counsel and Chair of the IRB and/or IACUC to determine whether certain aspects of the allegation should be handled by the IRB and/or IACUC and its representatives in parallel with the Research Misconduct Proceedings set forth in this policy. If at any point in a Research Misconduct Proceeding, the RIO determines that conduct in an allegation does not constitute Research Misconduct but raises concerns about the protection of human and/or animal subjects in research, then the allegation will be referred to the IRB and/or IACUC for investigation and resolution of such matters. If, in the course of IRB and/or IACUC duties, any IRB and/or IACUC members becomes aware of conduct that might constitute Research Misconduct, the Chair of the IRB and/or IACUC will similarly consult with the RIO and with the Office of General Counsel. These consultations should be made in compliance with the confidentiality obligations outlined in Section III.D below.

D. Confidentiality in Research Misconduct Proceedings

Maximum effort should be taken to preserve the confidentiality of the Research Misconduct Proceedings and information pertaining to the matter. NYMC cannot, however, guarantee the confidentiality of the identity of Complainant, Respondent, or any other person involved in any Research Misconduct Proceeding or of the information developed in the course of a Research Misconduct Proceeding.

To the extent possible, the identity of Respondents and Complainants shall be maintained securely and confidentially and no identifying information shall be disclosed, except to: (i) those who need to know in order to carry out a thorough, competent, objective, and fair Research Misconduct Proceeding; (ii) a funding sponsor, government agency, or enforcement body as may be required; (iii) as otherwise provided for in this policy; and (iv) as allowed by law. Any information obtained during the Research Misconduct Proceedings that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the Research Misconduct Proceedings or as otherwise allowed by law. The determination of those who need to know shall be made by NYMC, provided that NYMC makes such determination in good faith.

Without limiting the foregoing confidentiality protections, NYMC has complete authority to interact and communicate with, and disclose information to, federal agencies, academic journals, or other third parties to the extent that NYMC determines those third parties need to know the information. For example, the identity of the Respondent(s) and Complainant(s) will

be reported to ORI as required by law. Disclosure of any records or evidence from which research subjects might be identified is limited to those who have a need to know to carry out a Research Misconduct proceeding. The determination of those who need to know shall be made by NYMC, provided that NYMC makes such determination in good faith.

E. Protection of Complainants, Respondents, and Others; Consultation with Counsel

The RIO and other College Officials involved in the Research Misconduct Proceeding will make all reasonable and practical efforts to protect the rights and reputation of all parties involved in the allegation of Research Misconduct, including the Complainant and the Respondent, throughout the Research Misconduct Proceedings. It is NYMC's policy that no one shall suffer Retaliation for making a Good Faith allegation of Research Misconduct, or for providing testimony regarding the facts and circumstances surrounding the alleged Research Misconduct during an Inquiry or Investigation. Regardless of whether NYMC or ORI determines that Research Misconduct occurred, the RIO will undertake reasonable efforts to protect a Complainant who made an allegation of Research Misconduct in Good Faith and others who cooperate in Good Faith with Inquiries and Investigations of such allegations. Upon completion of an Investigation, the Deciding Official will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The RIO is responsible for implementing any steps the Deciding Official approves. (For discussion of the restoration of Respondent's reputation, see section V.B. below.)

Individuals accused of Research Misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. However, absent special exception, such legal counsel or personal advisers are not permitted to make presentations and are permitted to attend solely to confer with the Respondent at the Respondent's request and respond to directed questions from NYMC and/or Inquiry or Investigation Committees.

F. Ensuring a Fair Research Misconduct Proceeding

Reasonable steps shall be taken to ensure thorough, competent, objective, and fair Research Misconduct Proceedings to the maximum extent practicable. Those conducting the Inquiry or Investigation will be selected on the basis of scientific expertise or other experience that is pertinent to the matter and, prior to selection, shall be evaluated for any unresolved personal, professional, or financial conflicts of interest with the Respondent, Complainant, potential witnesses, or others involved in the matter. An individual shall also have the right to recuse him/herself.

VI. PROCEDURES FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

A. Summary of Research Misconduct Process

Once an allegation of Research Misconduct has been made, the RIO, working with the Office of General Counsel, shall promptly decide whether the allegation includes misconduct or deviation from policies, procedures, and regulations that rises to the level of Research Misconduct. Upon such determination, the following procedures will be undertaken pursuant to this policy:

1. Assessment of the allegation;
2. If the appropriate criteria are met, commencement of an initial Inquiry;
3. If the Deciding Official finds it is warranted based on the recommended findings of the Inquiry Committee, an Investigation to collect data and thoroughly examine the evidence; and
4. Issuance of the Deciding Official's final finding on the case and appropriate disposition.

If at any time during the initial Inquiry or the Investigation information is obtained that reasonably indicates the occurrence of possible criminal violations, the RIO shall notify the Office of General Counsel within twenty-four (24) hours. The Office of General Counsel shall assist the RIO in determining whether reports should be made to the appropriate office of the sponsoring or funding agency, ORI, appropriate law enforcement officials, or any other relevant organizations or agencies. If jurisdiction exists for PHS Supported Research, ORI must also be notified immediately if NYMC has reason to believe that any of the following conditions exist:

1. The health or safety of the public is at risk;
2. There is an immediate need to protect human or animal subjects;
3. HHS resources or interests are threatened;
4. There is reasonable indication of possible violations of civil or criminal law;
5. Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;
6. It is probable that the alleged incident will be reported publicly prematurely; or
7. The research community or public should be informed.

Additional reports shall be made as required by applicable federal, state, and local law. During the RIO's initial assessment of allegations, the RIO, in consultation with the Office of General Counsel, shall determine which government agencies, if any, have jurisdiction over the Research Misconduct Proceedings, based upon the funding source of the research to which the allegations apply.

B. Submission of Allegation

1. A Complainant may submit an allegation to the RIO or any College Official as set forth in Section III.A of this policy. The RIO may also identify an allegation based upon information received: (i) through informal communications with an individual or (ii) from a third party, whether internal or external to NYMC, including ORI or another governmental agency. If the RIO or College Official determines that the information provided by the potential Complainant constitutes an allegation subject to this policy, the RIO or College Official must pursue the allegation even if the potential Complainant chooses not to do so. If an allegation is submitted by the potential Complainant, it will be accepted and reviewed by a College Official to determine whether a Research Misconduct Inquiry is warranted, regardless of that College Official's opinion of the merits of the allegation.
2. If, upon receipt of an allegation, it appears that the RIO has any unresolved personal, professional, or financial conflicts of interest with those involved in the allegation, the person conveying the information to the RIO or the RIO will notify the Chancellor and CEO, who shall appoint another qualified individual to serve as interim RIO with respect to the Research Misconduct Proceeding.
3. If, upon receipt of an allegation, it appears assessment will require or otherwise result in notification to the Respondent, prior to such notification the RIO will take reasonable and practical steps to obtain custody of, inventory, and sequester (collectively, to "Secure") Research Records and other evidence that may be necessary to conduct the Research Misconduct Proceeding. If the Research Misconduct Proceeding progresses beyond the allegation, additional Research Records may need to be Secured.
4. Upon receiving or identifying an allegation, the RIO must assess the allegation to determine if an Inquiry is warranted. An Inquiry is warranted if the allegation (i) falls within the definition of Research Misconduct; (ii) involves research that is subject to this policy; and (iii) and is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified. If the allegation meets these criteria, the RIO shall immediately select an ad hoc committee to conduct an Inquiry (the "Inquiry Committee"). If the RIO determines that an Inquiry is not warranted, the RIO shall close the matter or, if other policies of NYMC may be implicated, refer the matter to the appropriate department or College Officials.

C. Inquiry

1. The RIO may engage individuals from outside of NYMC to serve on the Inquiry Committee, in accordance with the confidentiality provisions set forth in Section III.D of this policy. The RIO shall take steps to ensure that the individuals selected to serve on the Inquiry Committee do not have real or apparent unresolved personal, professional, or financial conflicts of interest with the Respondent, Complainant, or essential witnesses. Prospective Inquiry Committee members should immediately disclose to the RIO any known conflicts of interest related to the Respondent, Complainant, or essential witnesses.
2. Prior to initiating the Inquiry, the RIO shall notify the Respondent of the membership of the Inquiry Committee and shall give the Respondent the opportunity to submit a written objection to any member within fourteen (14) days of Respondent's receipt of such notice, based on unresolved personal, professional, or financial conflicts of interest. The RIO shall make a final determination on whether a conflict exists and, if it does, will select another individual to serve on the Inquiry Committee. This notification to the Respondent may be combined with or separate from the notification specified in Section IV.C.3 below.
3. At the time of or before beginning an Inquiry (and after Securing the Research Records and evidence as described in Section IV.C.4 below), the RIO must make a good faith effort to notify the Respondent of the Inquiry in writing, if the Respondent's identity is known. If the identity of the Respondent (or additional Respondents) is not known at the beginning of the Inquiry and becomes known during the Inquiry, notification of the Respondent shall occur as soon as practicable. Such notification will include a statement of the allegation(s) made against the Respondent and a description of the Inquiry process.
4. To the extent it has not already done so at the allegation stage, NYMC must, on or before the date on which the Respondent is notified of the Inquiry (as described in Section IV.C.3 above) or the Inquiry begins, whichever is earlier, promptly Secure all the Research Records and evidence needed to conduct the Research Misconduct Proceeding. When appropriate, at NYMC's discretion, the Respondent(s) may be given copies of, or reasonable, supervised access to, the Research Records and evidence.

5. The RIO will prepare a charge for the Inquiry Committee that sets forth the purpose of the Inquiry, the Inquiry Committee's responsibilities, the allegation(s), the standard for determining whether an Investigation is warranted, and the required timeframe for completion of the Inquiry. The purpose of the Inquiry is not to determine whether Research Misconduct definitely occurred or who was responsible. If applicable, the members of the Inquiry Committee may be told of the possibility that some or all of the Inquiry Committee members may later be asked to assume the responsibilities of an Investigation Committee. Inquiry by the Committee shall begin as soon as possible after the charge is received.
6. The RIO will support the Inquiry Committee and be available to answer questions but shall not participate directly in the determination of whether an Investigation is warranted. The RIO will instruct all involved (i) to take maximum efforts to conduct the Inquiry in a manner that is respectful and causes the least amount of disruption for all parties; (ii) to keep all information regarding the Research Misconduct Proceedings and the identity of the Complainant, Respondent, and any witnesses confidential in accordance with this policy; and (iii) to take steps to prevent Retaliation against the Complainant and any witnesses.
7. The Inquiry Committee shall conduct the Inquiry, which generally shall include interviewing the Complainant, the Respondent, and key witnesses, and examining relevant Research Records and materials. The Inquiry Committee will record or transcribe each interview and provide the recording or transcript to the interviewee for correction. However, not all available evidence must be pursued or reviewed at this stage. The Inquiry Committee may employ such outside resources (e.g., legal or consulting services) as it deems appropriate to assist in the Inquiry; the engagement of such resources should be coordinated through the Office of General Counsel and the RIO. The Inquiry should be completed within sixty (60) days of its initiation, unless the circumstances warrant a longer period. If the Inquiry takes longer than sixty (60) days to complete, the Inquiry record must document the reasons for the delay.
8. Upon conclusion of the Inquiry, the Inquiry Committee shall determine whether an Investigation is warranted. An Investigation is warranted when (i) there is a reasonable basis for concluding that the allegation falls within the definition of Research Misconduct; (ii) the allegation involves research that is subject to this policy; and (iii) preliminary information-gathering and fact-finding from the Inquiry indicates that the allegation may have substance. The Inquiry Committee's role is not to determine whether Research Misconduct actually occurred; rather, it is to determine

whether the evidence reviewed creates a reasonable concern that Research Misconduct may have occurred, warranting further fact-finding.

9. The Inquiry Committee shall document its determination in a final written report, as specified by the applicable regulations. The final report should generally identify the evidence reviewed, summarize relevant interviews, and state the recommended findings of the Inquiry Committee. The report must include sufficiently detailed information documenting the Inquiry Committee's recommendation as to whether further Investigation is warranted. The Respondent shall be provided with a copy of the Inquiry Committee's preliminary report, and the Respondent shall provide written comments within fourteen (14) days of receipt, unless the Inquiry Committee, in consultation with the RIO, grants an extension under extenuating circumstances. The Complainant may, at the Inquiry Committee's discretion, be provided with a summary or portions of the Inquiry Committee's preliminary report, if applicable, for comment within fourteen (14) days of receipt, unless the Inquiry Committee, in consultation with the RIO, grants an extension under extenuating circumstances. Any comments made by the Complainant or Respondent will be appended to the final report of the Inquiry Committee. Based on the comments, the Inquiry Committee may revise the report as it deems appropriate.
10. The final Inquiry report shall be promptly provided to the RIO for transmission to the Deciding Official. The Deciding Official will make a written determination as to whether an Investigation is warranted. If the Deciding Official concludes that an Investigation is warranted, he or she will direct the RIO to appoint an Investigation Committee. If the Deciding Official concludes that an Investigation is not warranted, NYMC shall maintain the final Inquiry report and sufficiently detailed documentation of the Inquiry to permit a later assessment of the reasons why an Investigation was not warranted.
11. The RIO shall notify the Respondent of the results of the Inquiry, including a copy of the final Inquiry report, applicable regulations, and this policy. Additionally, the RIO may, at the RIO's discretion, notify the Complainant of the results of the Inquiry and may share relevant portions of the report as necessary to communicate the results. If appropriate, the RIO may also notify publications to which results of implicated research have been submitted that an Investigation has been initiated.
12. To the extent required by applicable regulations, the RIO will notify the applicable regulatory agency or enforcement body of the decision to

begin an Investigation on or before the date the Investigation begins and shall provide a copy of the Inquiry report. For PHS Supported Research, on or before the date on which the Investigation begins, ORI must be notified and provided with the written finding by the Deciding Official and a copy of the Inquiry Committee's report, which must include: (i) the name and position of the Respondent(s); (ii) a description of the allegations of Research Misconduct, the PHS support (including grant numbers, grant applications, contracts, and publications listing PHS support); (iii) the basis for recommending that the alleged actions warrant an Investigation; and (iv) any comments on the report by the Respondent or the Complainant. If requested, NYMC must also provide to ORI: (a) the institutional policies and procedures under which the Inquiry was conducted; (b) the research records and evidence reviewed, including transcripts or recordings of any interviews, and copies of all relevant documents; and (c) the charges for the Investigation Committee to consider.

13. In some instances, the RIO may determine that it is unnecessary and would be inefficient for all involved to go through the procedures of an Investigation before concluding the matter. This may occur, for example, if the Respondent makes a full confession under circumstances that leave no reasonable questions as to the validity of the confession and the fact that Research Misconduct occurred; where the evidence presented during the Inquiry is otherwise particularly unambiguous and/or compelling; or where the Inquiry Committee did an exhaustive review of the available evidence in order to meet its charge and determines that there would be no additional evidence to review during a subsequent investigation that could materially impact a conclusion regarding whether Research Misconduct occurred. In such situations it may be appropriate for the Deciding Official to make a finding of Research Misconduct without proceeding through an Investigation. In such cases where no PHS support is involved, the RIO may recommend that the Deciding Official make a finding in the case based on the Inquiry Committee's report. The RIO shall state in writing the reasons why he or she believes that an Investigation is not necessary. If the Deciding Official concurs, he or she may make a finding in the case based on the Inquiry Committee's report. In such circumstances, the final Inquiry Committee report shall be deemed the equivalent of the final Investigation Committee report for the remainder of this policy. In such cases where PHS support is involved, it may be appropriate to come to a conclusion of Research Misconduct without proceeding through an Investigation solely in the circumstances of an unambiguous confession by the Respondent, provided that:

- The RIO must notify ORI *in advance* of its intention to close the case at the Inquiry stage;
- The Inquiry Committee report is provided to the Respondent with a clear statement that normally in cases involving PHS support the College does not make a finding of Research Misconduct without conducting an Investigation, but that in the present case it intends to make such a finding based on the Respondent's unambiguous confession;
- The Respondent makes no objection to this process within 14 days of receipt of the draft Inquiry report; and
- The confession is fully documented in the record with the Respondent acknowledging that the alleged actions constitute Research Misconduct.

If the Respondent objects in writing to this process on the basis of reasonable grounds, or if ORI determines that further action is necessary to examine the evidence or resolve the outstanding issues, the matter shall proceed to the Investigation stage notwithstanding the RIO's determination to the contrary. For PHS Supported Research, under no circumstances shall NYMC and the Respondent enter into any type of settlement with terms that require confidentiality or otherwise prohibit NYMC from communicating with ORI regarding the outcome of the proceedings.

D. Investigation

1. If the Inquiry Committee recommends and the Deciding Official determines that further examination and evaluation of the facts underlying the allegation is necessary, an Investigation shall be initiated within 30 days of the determination that an Investigation is warranted.
2. The RIO shall convene the Investigation Committee to conduct an Investigation. The RIO may engage individuals from outside of NYMC to serve on the Investigation Committee, in accordance with the confidentiality provisions set forth in Section III.D of this policy. If appropriate, the Inquiry Committee may be reconstituted by the RIO as the Investigation Committee; alternatively, some or none of the members of the Inquiry Committee may also serve on the Investigation Committee. The RIO shall take steps to ensure that the Investigation Committee includes one or more individuals with appropriate scientific expertise, and that individuals selected to serve on the Investigation Committee do not have unresolved personal, professional, or financial conflicts of interest with the Respondent, Complainant, or essential witnesses.

Prospective Investigation Committee members should immediately disclose to the RIO any known conflicts of interest related to the Respondent, Complainant, or essential witnesses.

3. Prior to initiating the Investigation, the RIO shall notify the Respondent of the allegations (including any new allegations) and the membership of the Investigation Committee and shall give the Respondent the opportunity to submit a written objection to any member of the Inquiry Committee within fourteen (14) days of Respondent's receipt of such notice, based on unresolved personal, professional, or financial conflicts of interest. The RIO shall make a final determination on whether a conflict exists and, if it does, will select another individual to serve on the Investigation Committee. The RIO shall also notify the Respondent that the Respondent may designate an individual as an advocate to counsel and confer with the Respondent, consistent with Section III.E of this policy.
4. The RIO will prepare a charge for the Investigation Committee that sets forth the purpose of the Investigation, the Investigation Committee's responsibilities, the allegation(s), the standard for determining whether Research Misconduct occurred, the relevant burden of proof, and the required timeframe for completion of the Investigation. The charge shall require that the Investigation Committee use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all Research Records and evidence relevant to reaching a decision on the merits of the allegation(s).
5. The RIO will serve as support staff to the Investigation Committee and be available to answer procedural questions but shall not participate directly in the determination of whether Research Misconduct occurred. The RIO will instruct all involved (i) to take maximum efforts to conduct the Investigation in a manner that is respectful and causes the least amount of disruption for all parties; (ii) to keep all information regarding the Research Misconduct Proceedings and the identity of the Complainant, Respondent, and any witnesses confidential; and (iii) to take steps to prevent Retaliation against the Complainant and any witnesses. The Office of General Counsel will be available, as needed, to advise on Committee proceedings.
6. The Investigation Committee shall conduct the Investigation, which shall include (i) diligently pursuing all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible Research Misconduct, and continuing

the Investigation to completion and (ii) interviewing Respondent(s), Complainant(s), 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 recording or transcribing each interview, providing the recording or transcript to the interviewee for correction, and including the recording or transcript, with any corrections appended, in the record of the Investigation. The Investigation Committee may employ such outside resources (e.g., legal or consulting services) as it deems appropriate to assist in the Investigation; the engagement of such resources should be coordinated through the Office of General Counsel and the RIO.

7. The Investigation should be completed within 120 days of initiation (or as dictated by the applicable funding agency), including conducting the Investigation, preparing the report of findings, providing the draft report for comment, and if required by applicable regulations, sending the final report to the applicable regulatory agency or enforcement body. For PHS Supported Research, if NYMC is unable to complete the Investigation in 120 days, NYMC will ask ORI for an extension in writing and will notify the Respondent of the revised timeframe. If ORI grants an extension, it may direct NYMC to file periodic progress reports.
8. When the Investigation Committee makes a recommended finding regarding the allegation of Research Misconduct, it shall submit a preliminary report reviewing all information and its recommended finding to the Respondent for written comment. The preliminary report shall adequately detail the evidence that supports or refutes each allegation included in the Investigation. NYMC may, to the extent possible, redact the identities of material witnesses in any evidence made available to the Respondent to protect the confidentiality of the witnesses' involvement in the Research Misconduct Proceedings. The Respondent will have thirty (30) days to comment on the preliminary report. A draft of the preliminary report (or a summary or portions thereof) also may, at the Investigation Committee's discretion, be made available to Complainant, with any comments to be submitted by the Complainant within fourteen (14) days. Any comments by the Respondent and/or Complainant shall be considered by the Investigation Committee before the Investigation report is finalized and shall be included in the final report.
9. Within ten (10) days of receiving comments from the Respondent and Complainant, if any, the Investigation Committee shall prepare and submit a final report, including any factual findings and

recommendations as to whether Research Misconduct should be found to have occurred, along with the Respondent's comments, if any, to the RIO. The RIO will submit the final Investigation report to the Deciding Official, along with a recommendation regarding any notifications that should be made (for example, government agencies or enforcement bodies, relevant journals, co-authors).

10. Upon review of the final Investigation report, the Deciding Official will make a written determination (i) as to whether NYMC accepts the findings and recommendations of the Investigation report; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct, in accordance with Section V.A of this policy.
11. The RIO will provide the final Investigation report with all attachments to the federal agency or other sponsor funding the research under question, if any, as well as to the Respondent. Additionally, the RIO may, in the RIO's discretion, notify the Complainant of the results of the Investigation and may share relevant portions of the report as necessary to communicate the results.
12. The RIO or their authorized delegate shall provide a summary report of the Investigation Committee's findings to the Department Chairperson, the Dean, the Chancellor, and the President of the College (the full report will be available upon request).

VII. CONSEQUENCES OF INVESTIGATION

A. Administrative and/or Disciplinary Actions

If the Deciding Official finds that Research Misconduct has occurred pursuant to the procedures set forth in this policy, the Deciding Official will decide on the appropriate administrative or disciplinary actions to be taken, if any, after consultation with the RIO and Office of General Counsel, and taking into consideration the recommendations of the Investigation Committee. The actions may include, but are not limited to:

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found;
2. Removal of the responsible person from the particular project (assuming it is ongoing);
3. Letters of reprimand, special monitoring of future work, probation, or suspension;
4. Salary reduction;

5. Initiation of steps leading to possible rank reduction or termination of employment;
6. Notification to hospitals and sponsoring agencies with which the individual has been or is affiliated and/or initiation of a review of prior research conducted at NYMC by the individual, if there is reason to believe that previous research may be characterized by Research Misconduct; and
7. Restitution of funds, as appropriate, to granting agencies, NYMC and/or research subjects.

The RIO shall notify the Respondent in writing of any administrative or disciplinary actions to be taken and shall also meet with the Respondent to discuss the Investigation Committee's recommended findings and the implementation of any such administrative or disciplinary actions. NYMC will assist ORI / HHS in administering and enforcing any HHS-authorized administrative actions.

B. Restoration of Respondent's Reputation

If the Deciding Official's finding is that no Research Misconduct occurred, and if the Inquiry or Investigation has resulted in any damage to the Respondent's reputation, the Respondent shall meet with the RIO to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. Any College actions to restore the Respondent's reputation must first be approved by the Deciding Official. The implementation of such approved actions will be the responsibility of the RIO. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the Inquiry or the Investigation of the final outcome, publicizing the final outcome in forums in which the allegation of Research Misconduct was previously publicized, or expunging all reference to the Research Misconduct allegation from the Respondent's personnel and/or departmental file.

VIII. OTHER CONSIDERATIONS

A. Termination of Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's NYMC employment or affiliation, by resignation or otherwise, before or after an allegation of possible Research Misconduct is made, will not preclude or terminate the Research Misconduct Procedures, due to the compelling interests of NYMC, research colleagues, the IRB or other research review committee, and research subjects in resolving such allegations.

If the Respondent refuses to participate in the process after resignation or otherwise, the Inquiry and Investigation Committees will use their best efforts to reach a conclusion concerning the

allegations, noting in their reports the Respondent's failure to cooperate and its effect on the Committee's review of all the evidence.

B. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the Complainant's allegations were made in Good Faith. If an allegation was not made in Good Faith, the Deciding Official will determine whether any administrative and/or employment action should be recommended against the Complainant. Submission of a Research Misconduct allegation with malicious intent or for personal enrichment or aggrandizement shall be grounds for an investigation or sanctions in accordance with applicable College policies.

IX. RECORD RETENTION

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including all relevant evidence secured in the course of the Investigation; documentation regarding any evidence no longer in the record due to its irrelevance or duplication; the Inquiry final report, including any finding not to investigate; the Investigation final report and all supporting records, including transcripts or recordings of all interviews; and the complete record of any appeal. The RIO will keep the file in a secure manner for seven years after completion of the case, or longer if required by applicable law, to permit later assessment of the case. ORI or other authorized government personnel will be given access to the records as required by law.

X. EFFECTIVE DATE

This policy is effective immediately.

XI. POLICY MANAGEMENT

Responsible Executive: Vice President of Research
Responsible Office: Office of Research Administration