Policy 7.8
Policy on Research Misconduct

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Responsible Official: VP for Research Administration
Administering Division/Department: Research Compliance
Effective Date: May 15, 2008
Last Revision: June 10, 2008

Policy Sections:

I. Overview
II. Applicability
III. Policy Details
IV. Definitions
V. Related Links
VI. Contact Information
VII. Revision History

Overview

This policy sets forth the policies and procedures that should be followed in reporting, inquiring into and investigating allegations of research misconduct and/or violation of research related laws, regulations or policies.

Applicability

This Policy and Procedure (the Policy) applies to all Institutional Members as that term is defined herein.

This document sets forth procedures for handling different types of Allegations of Research Misconduct (e.g., fraud, falsification and plagiarism) and/or allegations that Research laws, regulations or policies have been violated. The procedure to be followed for handling specific allegations will depend on the nature of the allegations. Federal regulations require that certain procedures be followed in handling Allegations of Research Misconduct involving Research that receives federal funding, and these procedures incorporate those requirements as appropriate.

Policy Details

This document is divided into sections. Sections 7.8.01, 7.8.02 and the Policy Definitions Section of this document set forth definitions, general principles and roles and responsibilities that apply to all proceedings under this document, no matter what the nature of the allegations or the source of funding of the Research involved.

Section 7.8.01 sets forth the procedure for reporting Allegations of Research Misconduct or Regulation/Policy Violations, as well as Emory’s policy prohibiting retaliation against anyone who reports any such allegations in Good Faith.

Section 7.8.02 describes the roles and responsibilities of key persons and committees in implementing these procedures.

Section 7.8.03 sets forth the procedure for handling Allegations of Research Misconduct. The summary set forth below provides assistance in determining when the procedure in Section 7.8.03 should be followed:
The procedure in **Section 7.8.03** will apply if the allegations received concern *Research Misconduct*, as defined in the **Policy Definitions Section** below.

**Section 7.8.03** is designed to comply with federal regulatory requirements for the conduct of *Inquiries and Investigations into Allegations of Research Misconduct Involving Federally-Sponsored Research* and it is based in part on the Office of Research Integrity’s “Sample Policy and Procedures for Responding to Allegations of Research Misconduct.” found at [http://ori.dhhs.gov/policies/ori_policies.shtml](http://ori.dhhs.gov/policies/ori_policies.shtml).

**Section 7.8.04** sets forth the procedure for handling allegations of violations of *Research*-related laws, regulations or policies. The summary set forth below provides assistance in determining when the procedure in **Section 7.8.04** should be followed:

The procedure in **Section 7.8.04** will apply if the allegations received do not concern *Research Misconduct*, but rather concern *Other Allegations*, as defined in **Policy Definitions Section**.

**Multiple Allegations of Different Types:** If the allegations received include some that would fall under the procedure in **Section 7.8.03** and some that would fall under the procedure in **Section 7.8.04**, then the **Administrative Official**, at his/her option, can:

a. Permit any **Inquiry Committee** established under **Section 7.8.03** to also serve as the **Institutional Review and Investigation Committee** under **Section 7.8.04** for the purposes of reviewing the allegations that fall under **Section 7.8.04** in accordance with the procedures set forth in that section; or

b. Establish an **Inquiry Committee** (and, if necessary, an **Investigation Committee**) to review allegations falling under **Section 7.8.03**, and establish a separate **Institutional Review and Investigation Committee** to review the allegations falling under **Section 7.8.04**.

**Section 7.8.01**

**Statement of Policy and General Principles**

**A. Use of Capitalized/Italicized Words:** This **Policy and Procedure for Receipt and Handling of Allegations of Research Misconduct and/or Violations of Research-Related Laws, Regulations or Policies** is referred to throughout this document as the **Policy**. The meanings of all other capitalized, italicized terms used in this **Policy** are set forth below in **Policy Definitions Section**.

**B. Statement of Policy:** The validity of *Research* and other scholastic endeavors is based on the implicit assumption of honesty and objectivity by the investigator and on the explicit premise that *Research* data can be verified. An academic institution and its faculty, students and staff must uphold this principle and endeavor to maintain public trust in the *Research* process.

An academic institution’s primary responsibility is to create and maintain an academic environment that fosters ethical behavior in scholarship and serves to prevent misconduct in *Research* and to promote *Research* that is carried out in accordance with all applicable regulations and policies. In order to carry out this responsibility, faculty, staff and students should immediately report any evidence of misconduct in *Research* or violations of *Research*-related policies and regulations to the appropriate administrative officials of Emory University (hereafter also referred to as “Emory,” “University,” or the “Institution”). These officials, in turn, should promptly review, inquire into and/or investigate any allegation that they receive.

This **Policy** sets forth the procedures that should be followed in reporting, inquiring into, and investigating such allegations. The procedures to be followed in a specific matter are determined by the nature of the allegations involved. Matters that involve *Allegations of Research Misconduct* will be conducted in accordance with the procedures set forth in **Section 7.8.03** of this **Policy**. Matters that do not involve *Allegations of Research Misconduct*, but rather involve *Other Allegations* will be conducted in accordance the procedures set forth in **Section 7.8.04** of this **Policy**.

**C. General Principles:** The following general principles will apply to all proceedings under this **Policy**:

1. **Responsibility to Report Research Misconduct or Regulation/Policy Violations:** All *Institutional Members* to whom this **Policy** applies should immediately report any observed or suspected *Research Misconduct or Regulation/Policy Violation* to their supervisor, the chair or chief administrator of their department, the dean/director of their unit, or directly to the **RIO**. If an allegation is initially reported to any one other than the **RIO**, then that person, in turn, should report the allegation to the **RIO**. Similarly, if the **RIO** initially receives a report, then s/he should notify the appropriate **Administrative Official** and any other appropriate administrators and/or University committees or units that may have jurisdiction over the issue.

If an individual is not sure whether or not a particular incident or practice constitutes *Research Misconduct* or a *Regulation/Policy Violation* that is covered by this **Policy**, then s/he may call the **RIO** to discuss the matter confidentially and obtain guidance. Such calls may be made anonymously.

Contact information for the **Research Integrity Officer** is as follows:
In addition, individuals may make anonymous reports through the Emory University Trust Line by calling 1-888-550-8830. The Trust Line is operated by an independent third party who will maintain the caller’s anonymity, while ensuring that the caller’s report is routed to the proper individuals within the University.

2. Responsibility to Cooperate with Inquiries, Investigations and Institutional Reviews and Investigations: All Emory University employees, faculty, students, agents, and other Institutional Members are obliged to cooperate fully with the RIO, Administrative Official and other institutional officials in the review of allegations and the conduct of any proceedings under this Policy. Such persons also are obligated to provide any relevant Evidence to the RIO, any Inquiry Committee, any Investigation Committee, any Institutional Review and Investigation Committee, and any other University unit or committee with jurisdiction regarding the matter at issue, as well as any appropriate governmental regulatory or funding agency.

3. Inform Researchers and Administrators of this Policy: Emory University shall work to ensure that its faculty, staff, students and administrators who are involved in Research are aware of and familiar with this Policy and any changes there to. Emory also shall stress to all such persons and administrators the importance of complying with this Policy.

4. Administrative Actions/Sanctions: At any time during or after an Inquiry, Investigation, Research Misconduct Proceeding or Institutional Review and Investigation or other proceeding under this Policy, Emory University, on its own initiative or in consultation with appropriate governmental agencies, reserves the right to take any Administrative Actions/Sanctions necessary to protect the health and safety of Research subjects; to protect the funds or resources of sponsors; to protect the University’s reputation and academic integrity; to protect the integrity of the Research process; to comply with any applicable governmental laws, regulations or policies; and/or to comply with any contractual obligations. These actions may include, but are not limited to, additional monitoring of the Research process and the handling of funds and equipment; reassignment of personnel or of the responsibility for the handling of funding/resources; additional review of Research data and results; withdrawal of pending abstracts; manuscripts, publications, and grant applications; and suspension of a Respondent (provided, however, that suspension prior to the completion of an Investigation or Institutional Review and Investigation shall be without interruption of salary or benefits).

5. Notification of Government Agencies and Sponsors: If the allegations received are Allegations of Research Misconduct relating to Research that receives support from a sponsor other than Emory University, then the RIO will make the following notifications to Research sponsors (specifically including but not limited to ORI and the NSF OIG):

- Notification on or before the initiation of a Investigation regarding Allegations of Research Misconduct;
- Notification of special circumstances, as set forth in Section 7.8.01-C.6 below.
- Notification of the findings of Research Misconduct at the conclusion of an Investigation or of findings of a Regulation/Policy Violation at the conclusion of an Institutional Review and Investigation.

6. Notification of Special Circumstances: At any time during any phase of a Research Misconduct Proceeding or other proceeding conducted under this Policy, the RIO will notify the Administrative Official, any government agency that is supporting the Research, or any other Research sponsor, if any of the circumstances set forth below exist. In the case of Research receiving PHS Support the RIO shall provide notice to ORI and in the case of Research receiving NSF Support, the RIO will notify the NSF OIG. Circumstances requiring notification are as follows:
   a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
   b. The resources or interests of any governmental agency providing support to the Research including, but not limited to HHS, PHS or NSF, are threatened.
   c. Research activities should be suspended.
   d. There is a reasonable indication of possible violations of civil or criminal law.
e. In the case of Federally-Sponsored Research, the federal government’s action is required to protect the interests of those involved in Research Misconduct Proceedings.

f. In the case of Federally-Sponsored Research, the Institution believes that a Research Misconduct Proceeding may be made public prematurely so that the federal government may be required to take appropriate steps to safeguard Evidence and protect the rights of those involved.

g. The research/scientific community or public should be informed, as determined by the Institution or appropriate government agency.

7. Relationship Between this Policy and Federal Regulations: Federally-Sponsored Research projects are subject to specific laws, regulations and policies (collectively, Governmental Requirements). In the case of Federally-Sponsored Research supported by funding from the PHS, the applicable Governmental Requirements are set forth at 42 CFR Part 93, which can be found at [http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr93_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr93_06.html).

In the case of Research supported by funding from the NSF, the applicable Governmental Requirements are set forth in 45 CFR Part 689, which can be found at [http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr689_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr689_06.html).

In some cases, Governmental Requirements specify that certain provisions be set forth within this Policy, and Emory has incorporated those requirements herein. From time to time, the University shall review this Policy in order to cause the Policy to remain in conformance with such requirements. If, however, there is, at any time, a conflict between such Governmental Requirements and this Policy, the Governmental Requirements shall supersede this Policy and must be followed with regard to any matters on which this Policy and such Governmental Requirements differ.

8. Non-Exclusivity of this Policy: Particular allegations and events may fall within the scope of more than one University policy and/or more than one set of Governmental Requirements. In addition, more than one University unit or government regulatory entity may have jurisdiction over certain allegations or events. Accordingly, the fact that proceedings are brought under this Policy does not preclude additional proceedings before other University units or committees and/or under other policies or regulations. For example, certain allegations regarding Research involving human subjects may fall within the scope of this Policy and within the scope of policies and procedures set forth by the Emory Institutional Review Board (IRB). In any case in which another University unit or committee may have jurisdiction pursuant to another applicable regulation or policy, the Administrative Official may, with the concurrence of that University unit or committee, combine the fact-finding proceedings under the other policy with those under this Policy by permitting a representative from that unit or committee to serve as a member of any Inquiry Committee, Investigation Committee, and/or and Institutional Review and Investigation Committee established under this Policy, and to report the facts found in such Inquiry, Investigation or Institutional Review and Investigation back to the University unit or committee for possible adoption.

9. Confidentiality: The RIO, Administrative Official, Committee Members and other institutional officials involved in the conduct of proceedings under this Policy shall limit the disclosure of the following information to those who need to know in order to fulfill requirements of the Policy, fulfill any applicable Governmental Requirements, respond to any subpoena or other legal request for information/materials, and to carry out any proceeding conducted under this Policy in a thorough, competent, fair and objective manner:

   a. The identity of the Complainant (if known) and the Respondent; and

   b. Any records or Evidence from which Research subjects might be identified.

The RIO may use written confidentiality agreements or other mechanisms to ensure that a recipient does not make any further disclosure of identifying information.

10. 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. The Administrative Official and other appropriate University officials shall cooperate with the RIO in ensuring that retaliation does not occur.

11. Protecting the Respondent: The Administrative Official involved in the conduct of proceedings under this Policy will make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in Research Misconduct or Regulation/Policy Violations, but against whom no finding of Research Misconduct or Regulation/Policy Violation is made.

SECTION 7.8.02
Roles and Responsibilities:
Set forth below are the various persons and committees who are involved in proceedings under this Policy, along with a description of their responsibilities.

1. **Research Integrity Office or RIO**: The Director of the Office of Research Compliance will serve as the RIO. The RIO shall be familiar with this Policy and with other applicable Governmental Requirements and Emory policies. The RIO shall be responsible for the general oversight and administration of proceedings under this Policy. The RIO’s responsibilities shall include the following activities:

   a. Consult confidentially with persons uncertain about whether to submit an allegation of Research Misconduct or Other Allegations.


   c. Assess any allegations received to determine whether they fall within the scope of this Policy, and if so the applicable procedural section of this Policy that should be followed with respect to examining the allegations.

   d. Consult with the proper Administrative Official regarding the initiation and administration of any necessary Inquiry, Investigation or Institutional Review and Investigation.

   e. Make any notifications and reports to governmental officials, sponsors and/or University officials, committees or units required by this Policy, applicable Government Requirements or other University policies.

   f. Inform Respondents, Complainants, and witnesses of procedural steps in the Research Misconduct proceeding or other proceedings under this Policy.

   g. Sequester Research data and Evidence pertinent to the allegations received and maintain it securely in accordance with this Policy and applicable Governmental Requirements.

   h. Maintain records of Research Misconduct Proceedings and other proceedings carried out under this Policy in accordance with any applicable record retention requirements set forth in Emory policies or applicable Governmental Requirements and make such records available to appropriate governmental agencies as required by applicable Governmental Requirements.

   i. Assist any Inquiry Committee, Investigation Committee and Institutional Review and Investigation Committee in complying with this Policy and with all other applicable Governmental Requirements and Emory policies.

   j. Work to ensure the confidentiality of the proceedings and to maintain the security and confidentiality of records of proceedings carried out under this Policy.

   k. Take any other actions necessary to carry out the duties of the RIO under this Policy.

2. **Administrative Official**: The Administrative Official for a particular proceeding under this Policy is the Dean or Director (or his/her designee) of the Emory school or unit in which the Respondent works (or, in the case of a student Respondent, is enrolled). In the event that Dean or Director of a school or unit is the subject of the allegations that are being made, then the appropriate Vice President (or his/her designee) shall serve as the Administrative Official. The Administrative Official, in consultation with other appropriate Emory administrators, shall be responsible for reviewing/implementing recommendations of any Inquiry Committee, Investigation Committee or Institutional Review and Investigation Committee and prescribing appropriate Administrative Actions/Sanctions, if any, in response to a committee’s findings. The Administrative Official’s responsibilities shall include the following activities:

   a. Provide confidentiality to those involved in any proceedings under this Policy in accordance with all applicable Governmental Requirements.

   b. In consultation with the RIO, appoint the chair and members of any Inquiry Committee, Investigation Committee and/or Institutional Review and Investigation Committee, and ensure that these committees are properly staffed with persons with appropriate expertise to carry out a thorough and authoritative evaluation of the Evidence.

   c. Determine whether each person involved in handling any allegations under this Policy has any unresolved personal, professional or financial conflict of interest and take appropriate action, including recusal to ensure that no person with such a conflict is involved in the proceedings.

   d. In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the position and reputation of any Good Faith Complainant, witness, Committee Member, and Respondent against whom no finding has been made, and counter potential or actual Retaliation against them by Respondent or other Institution Members;
e. Ensure that Administrative Actions taken by the Institution and appropriate governmental agencies are enforced.

f. Cooperate with the RIO in notification of other involved parties such as sponsors, appropriate governmental agencies, law enforcement agencies, journals and other publishers, and professional and licensing boards of Administrative Actions/Sanctions taken, as required by Governmental Requirements and University policies

g. Notify the Respondent of the proceedings and provide opportunities for him/her to review/comment/respond to allegations, evidence and committee reports.

h. Receive and evaluate any report provided by any Inquiry Committee, Investigative Committee and/or Institutional Review and Investigation Committee and take any action regarding such reports as is required pursuant to this Policy or any applicable Governmental Requirements. Specifically, the Administrative Official shall take the following actions with regard to each of the reports named below:

i. Inquiry Committee Report: Review the report and, in consultation with the RIO and other appropriate institutional officials, make an Administrative Determination regarding (a) whether to accept the Inquiry Committee’s findings as to whether an Investigation is warranted under the criteria set forth in applicable laws and University policies; (b) whether to accept any other of the Inquiry Committee’s recommendations; and (c) whether to impose any new or additional requirements. If an Investigation it to be initiated, the Administrative Official also shall ensure that the RIO sends any required notice of the initiation of an Investigation to ORI (and/or any other appropriate governmental agency) along with a copy of Inquiry Committee’s report.

ii. Investigation Committee Report: Review the report and, in consultation with the RIO and other appropriate institutional officials, make an Administrative Determination regarding (a) whether to accept the Investigation Committee’s findings; (b) whether to accept the Investigation Committee’s recommendations, including recommendations regarding Administrative Actions/Sanctions; and (c) whether to impose any new or additional requirements. As appropriate, the Administrative Official also shall ensure that the RIO notifies ORI (and/or any other appropriate governmental agency) in writing of the Administrative Official’s Administrative Determination with regard to findings and Administrative Actions/Sanctions and provides a copy of the Investigation Committee Report.

iii. Institutional Review and Investigation Committee Report: Review the report and, in consultation with the RIO and other appropriate institutional officials, make an Administrative Determination regarding (a) whether to accept the Institutional Review and Investigation Committee’s findings; (b) whether to accept the Institutional Review and Investigation Committee’s recommendations, including recommendations regarding Administrative Actions/Sanctions; and/or (c) impose new or additional requirements. The Administrative Official shall ensure that the RIO notifies any appropriate governmental agencies or other parties (e.g., sponsors) of the Administrative Official’s Administrative Determination regarding findings and Administrative Actions/Sanctions, and provides a copy of the report when required by applicable Governmental Requirements.

Take any other actions necessary to carry out the duties of the Administrative Official under this Policy.

3. Complainant: The Complainant is the person who brings any allegations forward under this Policy. The Complainant is responsible for making all allegations in Good Faith; for maintaining confidentiality; and for cooperating with any Inquiry Committee, Investigation Committee or Institutional Review and Investigation Committee. If the Complainant’s identity is known, the Complainant should be interviewed as a part of any Inquiry, Investigation or Institutional Review and Investigation conducted under this Policy. A Complainant may make allegations anonymously and request that anonymity be preserved throughout the proceeding. The RIO and any committee appointed under this Policy may take this fact into consideration in determining whether the allegations are substantive and/or brought in Good Faith.

4. Respondent: The Respondent is the person against whom allegations are brought. The Respondent is responsible for maintaining confidentiality and cooperating with the RIO and with any Inquiry, Investigation or Institutional Review and Investigation Committee. The Respondent should be interviewed as a part of any Inquiry, Investigation, or Institutional Review and Investigation conducted under this Policy.

5. Inquiry Committee: The Inquiry Committee shall conduct any Inquiry required under this Policy. The Administrative Official shall select the members and chair of any Inquiry Committee. In making this selection, the Administrative Official shall consult with the RIO and shall take care to ensure that all persons taking part in the Inquiry do not have real or apparent Conflicts of Interest and do have the necessary and appropriate expertise to properly conduct the Inquiry. If necessary, some or all members of the Inquiry Committee may be selected from outside the University. The Inquiry Committee is responsible for the following activities:

a. Following this Policy and all other applicable policies, procedures, and Governmental Requirements in
b. Providing a report at the conclusion of the Inquiry that meets all requirements of this Policy and any applicable Governmental Requirements. The report shall include findings, conclusions, and recommendations and shall be provided to the Administrative Official and to the RIO.

c. Taking all reasonable steps to conduct its Inquiry in a fair and impartial manner and to protect the confidentiality of all aspects of the proceedings.

6. Investigation Committee: The Investigation Committee shall conduct any Investigation required under this Policy. The Administrative Official in consultation with the RIO shall select the members of the Investigation Committee. The Administrative Official shall select the members and chair of any Investigation Committee. In making this selection, the Administrative Official shall consult with the RIO and shall take care to ensure that all persons taking part in the Investigation do not have real or apparent Conflicts of Interest and do have the necessary and appropriate expertise to properly conduct the Investigation. If necessary, some or all members of the Investigation Committee may be selected from outside the University. The Investigation Committee is responsible for the following activities:

a. Following this Policy and all other applicable policies, procedures, and Governmental Requirements in carrying out its Investigation duties.

b. Providing a report at the conclusion of the Investigation that meets all requirements of this Policy and any applicable Governmental Requirements. The report shall include findings, conclusions, and recommendations and shall be provided to the Administrative Official and to the RIO.

c. Taking all reasonable steps to conduct its Investigation in a fair and impartial manner and to protect the confidentiality of all aspects of the proceedings.

7. Institutional Review and Investigation Committee: The Institutional Review and Investigation Committee shall conduct any Institutional Review and Investigation required under this Policy. The Administrative Official shall select the members and chair of any Institutional Review and Investigation Committee. In making this selection, the Administrative Official shall consult with the RIO and shall take care to ensure that all persons taking part in the Inquiry do not have real or apparent Conflicts of Interest and do have the necessary and appropriate expertise to properly conduct the Institutional Review and Investigation. If necessary, some or all members of the Institutional Review and Investigation Committee may be selected from outside the University. The Institutional Review and Investigation Committee is responsible for the following activities:

a. Following this Policy and all other applicable policies, procedures, and Governmental Requirements in carrying out its Institutional Review and Investigation duties.

b. Providing a report at the conclusion of the Institutional Review and Investigation that meets all requirements of this Policy and any applicable Governmental Requirements. The report shall include findings, conclusions, and recommendations and shall be provided to the Administrative Official and to the RIO.

c. Taking all reasonable steps to conduct its Institutional Review and Investigation in a fair and impartial manner and to protect the confidentiality of all aspects of the proceedings.

SECTION 7.8.03
Procedures to be Followed for Matters Involving Allegations of Research Misconduct

A. Scope and Applicability of Section 7.8.03 of this Policy: Section 7.8.03 of this Policy is intended in part to carry out Emory University’s responsibilities under applicable federal regulations regarding handling of Allegations of Research Misconduct involving Federally-Sponsored Research, including 42 CFR Part 93 and 45 CFR §§ 689.1 to .10. Section 7.8.03 applies to matters in which all of the following elements are present:

1. Allegations of Research Misconduct. Allegations of Research Misconduct include allegations of Fabrication, Falsification or Plagiarism in proposing, performing or reviewing Research, Research proposals, or in reporting Research results;

AND

2. The Allegations of Research Misconduct concern a person who, at the time of the alleged Research Misconduct, was an Institutional Member.

B. Classification of Allegations: Upon receipt of any allegations, the RIO will perform an assessment to determine if the allegations are (1) Allegations of Research Misconduct involving an Institutional Member; (2) Other Allegations involving an Institutional Member; or (3) allegations that fall outside of the scope of this Policy. Allegations of Research Misconduct involving an Institutional Member will be handled in accordance with the procedure set forth in this Section 7.8.03. Other Allegations involving an Institutional Member shall be handled in accordance with Section 7.8.04 of this
Policy, and allegations that fall outside of the scope of the Policy shall be referred by the RIO to the appropriate university unit, committee or official for handling. In addition, the RIO shall refer to such other units, committees or officials those allegations which may fall both under this Policy and under the jurisdiction of any other University policy/committee.

C. Assessment of Allegations of Research Misconduct: Upon classifying an allegation as an Allegation of Research Misconduct that involves an Institutional Member, the RIO will promptly assess the allegation to determine whether it is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified. The assessment should be brief and completed promptly. In conducting the assessment, the RIO may but is not required to interview the Complainant, Respondent, or other witnesses. The RIO is not required to 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 the potential evidence of Research Misconduct may be identified.

D. Inquiry Procedure:

1. Initiation and Purpose of Inquiry: If the RIO determines that the criteria for an Inquiry are met then the RIO will notify and consult with the appropriate Administrative Official. If the Administrative Official concurs in the assessment, then the Administrative Official shall initiate the Inquiry. 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 Allegations of Research Misconduct.

2. Notice to Respondent, Complainant and Others: At the time of or before beginning an Inquiry, the Administrative Official shall make a reasonable, good faith effort to notify any known Respondent in writing. If the Inquiry identifies additional Respondents, they must be notified in writing. The Administrative Official also shall make a reasonable, good faith effort to notify the Complainant of the initiation of the Inquiry if the Complainant is known. If the Inquiry involves a published article or other document, any co-authors of the article/document who are not otherwise parties in the inquiry shall be notified as well.

3. Interim Administrative Actions/Sanctions and Notifications of Institution Officials, Government Agencies and Sponsors:

   a. The Administrative Official will notify the Dean/Director of his/her unit of the initiation of the Inquiry.
   b. The Administrative Official in consultation with the RIO shall take any appropriate Administrative Actions/Sanctions in accordance with Section 7.8.01-C.4.
   c. The RIO shall make any notifications of government agencies and sponsors in accordance with Section 7.8.01-C.5.

4. Sequestration of the Research Records: On or before the date on which the Respondent is notified of the allegations or the Inquiry begins, the RIO shall take all reasonable and practical steps to obtain custody of the Research Records and Evidence needed to conduct the Research Misconduct Proceeding; inventory the Research Records and Evidence; and sequester them in a secure manner, except that if the Research Records or Evidence encompass scientific instruments shared by a number of users, then 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.

5. Appointment of the Inquiry Committee: Promptly after the initiation of the Inquiry, the Administrative Official in consultation with the RIO shall appoint at least three members to form an Inquiry Committee and shall choose a committee Chair. The Inquiry Committee must consist of individuals who do not have unresolved personal, professional, or financial Conflicts of Interest with those involved with the Inquiry, and should include individuals with the appropriate expertise to evaluate the Evidence and issues related to the allegations, interview the Respondent, Complainant and key witnesses, and conduct the Inquiry. Some or all members of the Inquiry Committee may be selected from outside the University. Alternatively, the Administrative Official may appoint a standing committee that is authorized to conduct Investigations and to add or use members when necessary to provide the necessary expertise and/or to eliminate Committee Members with Conflicts of Interest.

6. Notification of Complainant and Respondent: The Administrative Official must make a reasonable, good faith attempt to notify the Complainant and the Respondent in writing of the names of persons who have been selected to serve as members of the Inquiry Committee. The Complainant and the Respondent shall have ten days from the receipt of this notice in which to provide the RIO with any written objection to the membership of the Inquiry Committee. If no objection is received within this period, then any objection on the part of the Complainant or Respondent to the Inquiry Committee shall be considered waived. If an objection is made, then in order for it to be considered, it must be made in Good Faith and must set forth in sufficient detail a reasonable basis for the objection (e.g., Conflict of Interest). The Administrative Official in consultation with the RIO shall consider any objection, and if they determine that the objection is reasonable, the Administrative Official shall appoint a new member of the Inquiry Committee. If they determine that the objection is not made in Good Faith and/or is unreasonable, the membership of the Inquiry Committee shall stand.
7. Charge to the Inquiry Committee and First Meeting: The RIO shall prepare a charge for the Inquiry Committee that:

a. Establishes a time for the completion of the Inquiry;

b. Describes the allegation against the Respondent and any related issues identified during the assessment process;

c. Advises the Inquiry Committee that the purpose of the Inquiry is to make a preliminary evaluation of the Evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is sufficient substantive evidence of possible Research Misconduct to warrant an Investigation;

d. Advises the Inquiry Committee that an Investigation is warranted if the Inquiry Committee determines that: (1) there is a reasonable basis for concluding that the allegation falls within the definition of Research Misconduct; and (2) the allegation may have substance, based on the Inquiry Committee’s review during the Inquiry;

e. Advises the Inquiry Committee that it should make a finding as to whether the allegations were made in Good Faith;

f. Advises the Inquiry Committee that it is responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this Policy and, in the case of Research receiving PHS Support, meets the requirements of 42 CFR §93.309(a);

g. Makes clear that the Inquiry Committee is not tasked with determining whether Research Misconduct occurred or if so, who was responsible; and

h. Makes clear that the Inquiry Committee must take all reasonable steps to ensure the confidentiality of the Research Misconduct Proceedings.

At the Inquiry Committee’s first meeting, the RIO shall review the charge, discuss the allegations and any related issues, review the appropriate procedures for conducting the Inquiry, and answer any questions raised by the Inquiry Committee. The RIO will assist the Inquiry Committee with organizing plans for the Inquiry. The RIO must be present or available throughout the Inquiry to advise the Inquiry Committee as needed.

8. Conduct of the Inquiry: The Inquiry Committee should interview the Complainant, Respondent, and relevant witnesses as well as reviewing pertinent regulations, Research Records and materials. The Inquiry Committee should evaluate the Evidence and testimony and, after consultation with the RIO, determine whether there is sufficient substantive Evidence of possible Research Misconduct to recommend further Investigation based on the criteria found in this Policy and the criteria found in any applicable Government Requirements (e.g., for Research receiving PHS Support, the criteria found in 42 CFR §93.307(d)). The scope of the Inquiry will not normally include deciding whether Research Misconduct actually occurred. However, if a legally sufficient admission of Research Misconduct is made by the Respondent, Research Misconduct may be determined at the Inquiry stage if all relevant issues are resolved. For Research receiving PHS Support, however, the RIO and Administrative Official shall consult with ORI regarding the next steps to be taken in such a case.

9. Inquiry Committee Procedures: The Inquiry Committee shall take care to keep sufficiently detailed documentation of the conduct of the Inquiry in order to permit a later assessment of the reasons for its determination as to whether an Investigation was necessary. Rules of evidence applicable in courts of law shall not apply in the conduct of the Inquiry, and although parties are free to consult with legal counsel at their own expense, legal counsel shall not be permitted to attend any interviews or other proceedings conducted by the Inquiry Committee. Legal counsel for the Respondent may only conduct interviews of persons employed by the University through arrangement with the University’s Office of the General Counsel and with the consent of the person to be interviewed.

10. Inquiry Committee’s Report: Once the Inquiry Committee has reviewed all Evidence and come to a conclusion as to whether an Investigation should be conducted, it must draft an Inquiry Committee Report that includes the following information:

a. The name and position of the Respondent;

b. A description of any federal support, including, in the case of Research receiving PHS Support, grant numbers, grant applications, contracts, and publications listing the PHS Support;

c. A description of the Allegations of Research Misconduct;
d. A description of the Evidence reviewed, a summary of all relevant interviews, and the basis for the Inquiry Committee’s conclusions and, findings, including findings as to whether the allegations were brought in Good Faith; and recommendations as to whether an Investigation should proceed; and

e. A recommendation as to other steps to be taken, if any. For example, if the Inquiry Committee determines that an Investigation is not warranted, it may recommend other actions to be taken. These recommendations may include, but are not limited to, recommendations with regard to the Complainant if the Inquiry Committee finds sufficient evidence to support a finding that the allegations against the Respondent were not made in Good Faith or recommendations regarding Administrative Actions/Sanctions.

The Inquiry Committee Report may be reviewed by University legal counsel for legal sufficiency and by the RIO for policy compliance. Modifications, if any, should be made by the Inquiry Committee after consultation with the RIO and University legal counsel.

11. Notification to the Respondent and Complainant and Opportunity to Comment: The RIO shall notify the Respondent of the recommendation of the Inquiry Committee as to whether an Investigation is warranted. The RIO will provide a draft of the Inquiry Committee Report to the Respondent for comment, and for Research receiving PHS Support the RIO shall include a copy of or a reference to 42 CFR Part 93. All respondents will be provided with a copy of Emory’s policies and procedures on Research Misconduct. The RIO will provide to the Complainant for comment a summary of the Inquiry Committee Report and/or relevant portions of the report regarding the Complainant’s testimony. The parties shall have ten days in which to provide their comments to the Inquiry Committee. The Inquiry Committee may, but is not required to, revise the Inquiry Committee Report based on the comments submitted. Any comments submitted will be attached to the Inquiry Committee Report and become a part of the Inquiry Record.

12. Transmittal of the Final Report: The Inquiry Committee will transmit the final Inquiry Committee Report to the Administrative Official and to the RIO.

13. Institutional Decision and Notification: After receipt and review of the Inquiry Committee Report and any comments from Respondent and Complainant, the Administrative Official, in consultation with the RIO and other appropriate institutional officials, shall make a written Administrative Determination as to (a) whether to accept the Inquiry Committee’s findings, including those regarding whether an Investigation is warranted; (b) whether to accept any other recommendations put forward by the Inquiry Committee; and (c) whether to impose any new or additional requirements. In making this Administrative Determination, the Administrative Official shall give considerable weight to the findings and recommendations of the Inquiry Committee. In the event that the Administrative Official rejects the Inquiry Committee’s findings and/or recommendations, he/she shall set forth in the written Administrative Determination the reasons therefor. The Inquiry is completed when the Administrative Official completes this Administrative Determination. The Administrative Official shall notify the Respondent and the Complainant in writing of the Administrative Determination and provide the RIO and Respondent with copies of the Administrative Determination and the final Inquiry Report.

14. Notification to Governmental Agencies: If the Administrative Official makes the Administration Determination to initiate an Investigation, then within thirty days of that finding, the RIO must notify any federal governmental agency that sponsors the Research involved in accordance with Section 7.8.01-C.5.

15. Decision not to Initiate an Investigation: If the decision is made not to initiate an Investigation, the University shall secure and maintain for seven years after termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment of the reasons why an Investigation was not conducted. For Research receiving PHS Support, these documents must be provided to ORI or other authorized HHS personnel upon request. The University also must notify PHS, other relevant PHS agencies or any other appropriate governmental agencies of any special circumstances that may exist pursuant to Section 7.8.01-C.6.

16. Time Limit for Inquiry Phase: By not later than sixty days after the date of the Inquiry Committee’s initial meeting, the Inquiry Committee should complete its conduct of the Inquiry and transmit the final Inquiry Committee Report to the Administrative Official and the Administrative Official should issue his/her Administrative Determination. If circumstances exist that require an extension of this sixty day period, then the Inquiry Committee shall make these circumstances known to the Administrative Official and the RIO, and the Administrative Official and RIO shall jointly decide whether the circumstances warrant the grant of an extension, and if so, the length of that extension. If an extension of time is approved, the RIO shall notify the Respondent and the Complainant and document in writing the reason for the extension for inclusion in the Records of Research Misconduct Proceedings. The Inquiry Committee Report also shall include a statement that an extension was provided and the reason therefor.

17. Record Keeping Requirements: The RIO shall keep all records from the Inquiry Committee or otherwise related to the Inquiry in a secure manner for at least three years after the later of the date on which the Inquiry or any
subsequent Investigation concludes, except those records retained as documentation of the decision not to initiate an Investigation, which are described in Section 7.8.03-D.15. All records shall be made available upon request to governmental agencies as may be required by, and in accordance with, all applicable Governmental Requirements.

18. Early Termination of an Inquiry: If the Inquiry Committee determines that circumstances (e.g., full retraction of allegations, admission of Respondent) make it appropriate to terminate the Inquiry early, then the Inquiry Committee may document its reasons for an early termination in a report and submit the report to the RIO and the Administrative Official for consideration and a decision as to whether the Inquiry may be terminated. In the case of Federally-Sponsored Research, a copy of the report also must be provided to the sponsor and early termination must be approved by the sponsor, the RIO and the Administrative Official. (Specifically, in the case of Research receiving PHS Support, a copy of this report should be provided to ORI for determination as to whether early termination is appropriate or further Inquiry or an Investigation is necessary.) The resignation or termination of a Respondent prior to the conclusion of an inquiry shall not in and of itself be sufficient justification to support the early termination of an Inquiry.

19. Restoration of Reputations: In the event that the Inquiry Committee determines that an Investigation is not warranted and no other violations are found, the University will diligently make appropriate efforts to restore the reputation of the Respondent and to protect the position and reputation of any Complainant who brought allegations in Good Faith.

E. Investigation Procedure:

1. Initiation of the Investigation: The Administrative Official and the RIO must initiate an Investigation by no later than thirty days after the determination by the Administrative Official that an Investigation should be initiated.

2. Purpose of the Investigation: The purpose of the Investigation is to develop a factual record by exploring the allegations in detail and examining the Research Records and all other evidence in depth, leading to recommended findings on whether Research Misconduct has been committed, by whom, and to what extent. The Investigation also will determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope of the Investigation beyond the original allegations.

3. Finding of Research Misconduct: In order to find that a Respondent has committed Research Misconduct, the Investigation Committee must find that (a) there was a significant departure from accepted practices of the relevant research community; and (b) the Research Misconduct was committed intentionally, knowingly or recklessly; and (c) the allegations are proved by a Preponderance of the Evidence.

4. Standard of Proof and Burden of Proof: The Institution has the burden to prove that the Respondent committed Research Misconduct by a Preponderance of the Evidence. The destruction, absence of, or Respondent’s failure to provide Research Records adequately documenting the questioned Research is Evidence of Research Misconduct when the Institution establishes by a Preponderance of Evidence that the Respondent intentionally, knowingly or recklessly had Research Records and destroyed them, had the opportunity to maintain the Research Records but did not do so, or maintained the Research Records and failed to produce them in a timely manner, and that the Respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community. The Respondent has the burden to prove, by a Preponderance of the Evidence, any affirmative defense that the Respondent may raise, including honest error or difference of opinion. The Investigation Committee will give due consideration to credible evidence of honest error or difference of opinion presented by the Respondent. The Respondent also has the burden to prove any mitigating factors that may be relevant to a decision to impose Administrative Actions or Sanctions.

5. Notifications: The RIO shall make the following notifications regarding the initiation of an Investigation:

   a. Notification to the appropriate Vice President, Provost and President of the University, as well as notification to the Dean/Director of the Respondent’s unit if he/she is not the Administrative Official.

   b. Within thirty days of the Administrative Official’s decision to initiate an Investigation, notification to sponsors and federal government agencies that support the Research involved, in accordance with the notification provisions of Sections III.C.5 and III.C.6 of this Policy. In the case of any such notification of the initiation of an Investigation provided to ORI or NSF OIG, the notification shall contain at least the following information: (1) the Administrative Official’s Administrative Determination; and (2) a copy of the Inquiry Committee Report and any comments thereon by the Respondent or the Complainant. The RIO shall provide the following information: (1) the name of the person against whom the allegations have been made; (2) the PHS or NSF application or grant numbers involved; (3) the University policies and procedures under which the Inquiry was conducted; and (4) the charges to be considered in the Investigation. In addition, at the request of ORI or the NSF OIG, the RIO shall provide the Research Records and Evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.
Investigation

10. and/or is unreasonable, the membership of the appoint a new member of the part of the membership of the Respondent convening of the

9. when necessary to provide the necessary expertise and/or to eliminate the evidentiary value of the instruments. In addition, if facts have arisen during the Inquiry that indicate that aspects of the matter should be referred to other Research Committees for review and/or action, then the RIO shall make such referrals.

7. Interim Administrative Actions and Sanctions: The Administrative Official in consultation with the RIO shall take any appropriate Administrative Actions/Sanctions in accordance with Section 7.8.01-C.4. The Administrative Official, in consultation with the RIO, also shall take any interim Administrative Actions/Sanctions that may be necessary to protect any federal funds or to ensure that the purposes of federal financial assistance are being carried out. In addition, the Administrative Official and the RIO shall review the allegations to determine whether they also fall under the jurisdiction of any of the University Research Committees, and the RIO shall make any referrals to such Research Committees that were not made during the Inquiry phase (see Section 7.8.03-B, above).

8. Appointing the Investigation Committee: The Administrative Official, in consultation with the RIO, shall, within ten days of the initiation of the Investigation or as soon thereafter as practical, appoint at least three members to form an Investigation Committee and shall choose a committee Chair. 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 expertise to evaluate the Evidence and issues related to the allegations, interview the Complainant and Respondent and key witnesses, and conduct the Investigation. Members of the Inquiry Committee shall be eligible to serve on the Investigation Committee. Some or all of the members of the Investigation Committee may be selected from outside the University. Alternatively, the Administrative Official may appoint a standing committee that is authorized to conduct Investigations and to add or use members when necessary to provide the necessary expertise and/or to eliminate Committee Members with Conflicts of Interest.

9. Notifying the Complainant and the Respondent: At the time of or before beginning an Investigation, the RIO must make a reasonable, good faith effort to notify the Complainant and the Respondent in writing of the convening of the Investigation and the membership of the Investigation Committee. The Complainant and the Respondent shall have ten days from the receipt of this notice in which to provide the RIO with any written objection to the membership of the Investigation Committee. If no objection is received within this period, then any objection on the part of the Complainant or Respondent to the Investigation Committee shall be considered waived. If an objection is made, then in order for it to be considered, it must be made in Good Faith and must set forth in sufficient detail a reasonable basis for the objection (e.g., Conflict of Interest). The RIO, in consultation with the Administrative Official, shall consider the objection, and if they determine that the objection is made in Good Faith and reasonable, they shall appoint a new member of the Investigation Committee. If they determine that the objection is not made in Good Faith and/or is unreasonable, the membership of the Investigation Committee shall stand.

10. Charge to the Investigation Committee and First Meeting: The RIO shall prepare a charge for the Investigation Committee that sets forth the following information:

a. Identifies the Respondent.

b. Describes the allegations and related issues identified during the Inquiry.

c. Defines Research Misconduct.

d. Advises the Investigation Committee that it must thoroughly evaluate the Evidence and testimony of the Respondent, Complainant, and relevant witnesses in order to determine whether, based on a Preponderance of the Evidence, Research Misconduct has occurred, and if so, to what extent, who was responsible, and how serious it was.

e. Advises the Investigation Committee that in order to determine that the Respondent committed Research Misconduct, it must find that a Preponderance of the Evidence establishes that: (1) Research Misconduct occurred; (2) the Research Misconduct was a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the Research Misconduct intentionally, knowingly, or recklessly.

f. Advises the Investigation Committee that the Respondent has the burden of proving by a Preponderance of the Evidence any affirmative defenses raised, including honest error or a difference of opinion;

g. Informs the Investigation Committee that it must take all reasonable steps to ensure
the confidentiality of the proceedings;

h. Informs the Investigation Committee that if during the Investigation, additional information becomes available that substantially changes the subject matter of the Investigation or suggests additional Respondents, then the Investigation Committee should notify the RIO, who in conjunction with the Administrative Official, will determine whether it is necessary to notify the Respondent of the new subject matter, or provide notice to additional Respondents.

i. Informs the Investigation Committee that it must prepare or direct the preparation of a written Investigation Committee Report that meets the requirements of this Policy and, in the case of Research receiving PHS Support, 42 CFR § 93.313 or, in the case of Research receiving NSF Support, 45 CFR § 689.4.

At the Investigation Committee’s first meeting, the RIO shall review the charge, discuss the allegations and any related issues, review the appropriate procedures for conducting the Investigation, and answer any questions raised by the Investigation Committee. The Investigation Committee will be provided with a copy of this Policy; 42 CFR Part 93 in the case of Research receiving PHS Support; and 45 CFR Part 689 in the case of Research receiving NSF Support. The RIO must be present during or available throughout the Investigation to advise the Investigation Committee as needed.

11. Conduct of the Investigation: The Investigation Committee should take the following actions:

a. Interview the Respondent and the Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent and Complainant; record or transcribe each interview; provide the recording or transcript to the interviewee for correction; and include the recording or transcript in the record of the Investigation.

b. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documents and includes examination of all Research Records and Evidence relevant to reaching a decision on the merits of each allegation. Such Research Records and Evidence should include pertinent regulations, Research Records, data, proposals, publications, correspondence, memoranda of telephone calls, and other materials, such as the records of the Inquiry Committee and a copy of the Inquiry Committee Report and attached comments.

c. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical.

d. Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any Evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion;

e. Evaluate the Evidence and testimony and determine whether, based on a Preponderance of the Evidence, Research Misconduct occurred, and if so, to what extent and its seriousness.

f. Prepare and maintain sufficient documentation regarding its conduct of the Investigation to substantiate the Investigation Committee’s findings, which documentation may be required to be made available to government agencies in accordance with applicable Governmental Requirements.

12. Legal Counsel: All parties may retain legal counsel at their own expense, and legal counsel may be present during the Investigation Committee’s interviews or proceedings, but legal counsel shall not be permitted to question interviewees or otherwise participate in the proceedings. Legal counsel may interview witnesses who are employees of the University only through arrangement with the University’s Office of General Counsel, and only with the consent of the witness.

13. Communications and Notifications During Investigation: During the course of any Investigation into Allegations of Research Misconduct, the Investigation Committee should keep the Administrative Official and the RIO apprised of any developments that disclose facts that may affect current or future governmental funding for the Respondent, or that appropriate governmental agencies may need to know to ensure the appropriate use of governmental funds and to protect the public interest. In turn, the RIO shall provide notice to the following entities regarding such developments: (a) NSF OIG in the case of Research receiving NSF Support; (b) ORI in the in the case of Research receiving PHS Support; and (c) other appropriate governmental agencies, in the case of Research receiving support from governmental agencies other than NSF or PHS.
14. Investigation Committee’s Report: The Investigation Committee and the RIO are responsible for preparing a written draft report of the Investigation that:

a. Describes the nature of the Allegation of Research Misconduct, including identification of the Respondent.

b. Describes and documents any PHS Support, NSF Support or other governmental support for the Research, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS Support.

c. Describes the specific Allegations of Research Misconduct considered in the investigation.

d. Includes the Institution’s policies and procedures under which the Investigation was conducted.

e. Identifies and summarizes the Research Records and Evidence reviewed and identifies any Evidence taken into custody but not reviewed.

f. Includes a statement of findings for each Allegation of Research Misconduct identified during the Investigation. Each statement of findings must: (1) indicate 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 the Respondent did not engage in Research Misconduct because of honest error or a difference of opinion; (3) identify any specific PHS Support, NSF Support or other governmental support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the Research Misconduct; and (6) list any current support or known applications or proposals for support that the Respondent has pending with any governmental agencies.

g. Includes a statement of a finding of Research Misconduct. The finding must include the following elements: (1) there must be a significant departure from accepted practices of the relevant research community; (2) the Research Misconduct must be committed intentionally, or knowingly, or recklessly, and (3) the allegation must be proven by a Preponderance of the Evidence.

h. Includes a description of the recommended Administrative Actions/Sanctions. The nature of the Administrative Actions/Sanctions recommended/imposed shall depend on the severity of the misconduct, and may range from a letter of reprimand to dismissal of the Respondent. Other Administrative Actions/Sanctions that may be imposed upon the Respondent include, but are not limited to, withdrawal of all pending abstracts and papers emanating from any Research tainted by Research Misconduct; restitution of funds to the funding agency as appropriate; notification of the editors of journals in which previous abstracts and papers were published; notification of institutions and sponsors with which the Respondent has been associated if there is reason to believe that the validity of previous Research might be questionable; and/or release of information about the incident to the press in cases in which health and safety issues or public funds were involved.

The Investigation Committee Report may be reviewed by University legal counsel for legal sufficiency and the RIO for policy compliance. Modifications, if any, should be made by the Investigation Committee after consultation with the RIO and University legal counsel.

15. Comments on the Investigation Committee Report: A draft of the Investigation Committee Report must be provided to the Respondent for comment, and the Respondent must either be provided with a copy of the Evidence on which the report is based or supervised access to that Evidence. The Respondent shall have thirty days from the date s/he received the draft report to provide comments to the Investigation Committee. The Respondent’s comments must be considered and included in the final report. A draft of the Investigation Committee Report, or relevant portions of it, may be provided to the Complainant for comment. The Complainant shall have thirty days from the date s/he received the draft report to provide comments to the Investigation Committee. The Complainant’s comments must be considered and included in the final report.

16. Transmittal of Final Investigation Committee Report; Administrative Determination; and
Implementation: The Investigation Committee shall transmit the final Investigation Committee Report to the Administrative Official with a copy to the RIO. After receipt and review of the Investigation Committee Report and any comments from Respondent or Complainant, the Administrative Official shall, in consultation with the RIO and other appropriate institutional officials, make a written Administrative Determination as to (a) whether to accept the Investigation Committee’s findings; (b) whether to accept any recommendations put forward by the Investigation Committee; and (c) whether to impose any new or additional requirements. In making this Administrative Determination, the Administrative Official shall give considerable weight to the findings and recommendations of the Investigation Committee. In the event that the Administrative Official rejects the Investigation Committee’s findings and/or recommendations, he/she shall set forth in the written Administrative Determination the reasons therefore, as well as the reasons for any new or additional requirements that the Administrative Official imposes. The Administrative Determination shall document any Administrative Actions/Sanctions that are to be imposed upon the Respondent, and the Administrative Determination document shall be added to the final Investigation Committee Report. The Investigation is finished when the Administrative Official completes this Administrative Determination. The Administrative Official shall notify the Respondent and the Complainant in writing of the Investigation Committee’s findings and the Administrative Determination and provide the RIO and Respondent with copies of the Administrative Determination and the final Investigation Committee Report. The Administrative Official also shall notify the appropriate Vice President, the Provost, and President of the Investigation Committee’s findings and the Administrative Determination.

If the Investigation Committee found that the Respondent committed Research Misconduct and the Research was Federally-Sponsored, then the RIO must, within the 120 day period for completing an Investigation, submit the following to PHS ORI, NSF OIG, and/or other appropriate government agency that sponsored the Research:

a. A copy of the final Investigation Committee Report with comments attached (including sanctions to be imposed);

b. A statement of whether the University accepts the findings of the Investigation Committee Report;

c. A statement of whether the University found Research Misconduct, and if so, who committed the Research Misconduct; and

d. A description of any pending or completed Administrative Actions/Sanctions against the Respondent.

e. After ORI, NSF OIG or other appropriate government agencies have been notified, the RIO 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.

17. Appeal: The Respondent shall have the right to appeal a finding of Research Misconduct to the Provost or the appropriate Vice President in charge of Respondent’s unit within ten days of receipt by the Respondent of the final Investigation Committee Report and the Administrative Official’s written determination. The only grounds for appeal are procedural error or substantive new Evidence in favor of the Respondent. The appeal must be in writing and must specifically enumerate the grounds for appeal and provide documentation or affidavits of any substantive new Evidence for consideration. If no appeal is received by the end of the ten day period, the Respondent shall be deemed to have waived any appeal rights. If an appeal is received in a timely fashion, the appropriate Vice President or Provost will appoint an Appeals Committee consisting of three individuals who have sufficient expertise to review the appeal and who do not have any Conflict of Interest with regard to the Respondent or the matter for review. Members of the Inquiry Committee or the Investigation Committee shall not be eligible to serve on the Appeals Committee. The Appeals Committee shall have thirty days within which to review the record of the Inquiry and Investigation proceedings, and the Respondent’s substantive new evidence (if any), and issue an Appeals Report to the Provost or Vice President that provides as follows:

a. If the Appeals Committee determines that the Investigation was not procedurally flawed and/or there is no substantive new Evidence that could justify reversing the decision of the Investigation Committee, then the appeal shall be denied.

b. If the Appeals Committee determines that there were procedural errors in the Investigation, or discovers substantive new Evidence that could justify reversing the decision of the Investigation, then the Appeals Committee may grant the appeal and recommend a new Investigation by the same or a different Investigation Committee.

18. Time Limit for Investigation Phase: By no later than sixty days after the date of the Investigation
Committee’s initial meeting, the Investigation Committee should complete its Investigation and submit its final report to the Administrative Official, and the Administrative Official should transmit the final report and the Administrative Determination (including a description of any Administrative Actions/Sanctions imposed) to the Respondent. The Respondent shall then have ten days from receipt of the final Investigation Committee Report and Administrative Determination within which to appeal any decision. The Appeals Committee shall have thirty days from the receipt of an appeal in which to grant or deny the appeal. If the appeal is denied, the final Investigation Committee Report, along with a notice of the denial of the appeal, must be provided to the Respondent and any federal government Research sponsor by not later than 120 days after the initial meeting of the Investigation Committee. In the case of Research receiving PHS Support, the notice shall be provided to ORI, and in the case of Research receiving NSF Support, notice shall be provided to NSF OIG.

19. Extension of Time for Investigation: If circumstances exist that require an extension of the 120-day period, the Investigation Committee shall tell the Administrative Official and the RIO about these circumstances. The RIO and the Administrative Official shall consider that request, and if they determine that the request is justified, then the RIO must submit any request for an extension of time to any federal sponsor in writing and include an explanation for requesting the extension; an interim report on the progress of the Investigation to date; and an estimate of the date of completion of the Investigation. When an Appeals Committee grants an appeal, the RIO shall automatically consider an extension of time and shall submit a request for an extension to any federal sponsor. In the case of Research receiving PHS Support, requests for extension of time shall be provided to ORI, and in the case of Research receiving NSF Support, requests shall be provided to NSF OIG. If the request for an extension is granted, the Investigation Committee (or the new Investigation Committee, as the case may be, in the event an appeal is granted) shall then be required to make periodic reports to the RIO on its progress, which in turn will forward to the federal sponsor. If an extension of time is approved, the RIO shall notify the Respondent and the Complainant and document in writing the reason for the extension and include this in the Investigation Committee Report.

20. Record Keeping Requirements: The RIO shall keep all records from the Investigation Committee or otherwise related to the Investigation in a secure manner for at least seven years after the date on which the Investigation (including any appeal thereof) concludes, or any PHS or NSF proceeding involving the Research Misconduct allegation is completed, whichever is later, unless ORI, NSF OIG or another applicable government agency notifies the University that it no longer needs to retain the records. All records shall be made available upon request to governmental agencies as may be required by, and in accordance with, all applicable laws. If the Respondent is found by the Investigation Committee to have committed Research Misconduct or a Regulation/Policy Violation and the Administrative Official accepts this determination, then this finding and a summary of the Investigation Committee’s report shall be placed in the Emory University personnel file of the Respondent.

21. Early Termination of an Investigation: If the Investigation Committee determines that circumstances (e.g., full retraction of allegations, admission of Respondent) call for it to consider terminating its Investigation then it may document its reasons for early termination in a report and submit the report to the RIO and Administrative Official for consideration and a decision as to whether the Investigation may be terminated. The RIO, in turn, shall submit a copy of the report to any federal sponsor (ORI in the case of Research receiving PHS Support and NSF OIG in the case of Research receiving NSF Support). Early termination must be approved by any federal sponsor, the RIO and the Administrative Official. The resignation or termination of a Respondent prior to the conclusion of an investigation shall not in and of itself be sufficient justification to support the early termination of an Investigation.

22. Restoration of Reputations: In the event that the Investigation Committee determines that no Research Misconduct has occurred, this determination is accepted by the Administrative Official and no other violations have occurred, then the University will diligently make appropriate efforts to restore the reputation of the Respondent and to protect the position and reputation of any Complainant who brought allegations in good faith.

SECTION 7.8.04
Procedures to be Followed for Matters Involving Other Allegations

A. Initial Assessment of Allegations: Upon receipt of allegations of a possible Regulation/Policy Violation (collectively referred to as “Other Allegations”), the RIO will promptly perform an assessment of the allegations to make the following determinations:

1. A determination as to whether or not the Other Allegations fall within the scope of this Policy; and

2. A determination as to whether or not the Other Allegations fall within the jurisdiction of any other Research Committee responsible for the oversight of Research at the University (e.g., IRB, IACUC, etc.).

B. Result of Initial Assessment: The RIO shall take one of the following actions depending on his/her initial assessment of the Other Allegations:

1. If the RIO determines that the Other Allegations do not fall within the scope of this Policy and do not fall within the jurisdiction of another Research Committee, the RIO shall document his/her determination and make such referrals to other persons/units within the University for handling of the Other Allegations as the RIO deems appropriate.

2. If the RIO determines that the Other Allegations do not fall within the scope of this Policy and do fall within the
jurisdiction of another Research Committee, the RIO shall make an appropriate referral of the Other Allegations to the appropriate Research Committee for handling.

3. If the RIO determines that the Other Allegations fall within the scope of this Policy and do not fall within the jurisdiction of another Research Committee, the RIO shall contact the appropriate Administrative Official and initiate the Institutional Review and Investigation process, as described below.

4. If the RIO determines that the Other Allegations fall both within the scope of this Policy and the jurisdiction of another Research Committee, the RIO in consultation with the appropriate Administrative Official and the Chair(s) of the appropriate Research Committee(s) shall either:

   a. Refer the Other Allegations to the appropriate Research Committee(s) for handling under the Research Committee(s)'s policies and procedures; or

   b. Review the Other Allegations under the Institutional Review and Investigation process set forth in this Policy and appoint a member(s) of the other Research Committee(s) to in consultation with the RIO to review the Other Allegations under this Policy and serve as a member(s) of the Institutional Review and Investigation Committee that reviews the Other Allegations and to report findings of fact back to the Research Committee(s) for consideration and recommended actions. Under this latter option, the Research Committee(s) shall not be required to have a separate fact-finding process.

C. Conduct of Initial Assessment: In conducting the initial assessment, the RIO should interview the Complainant, Respondent, and other witnesses, and review any data submitted with the allegation or otherwise readily available. The RIO shall make this review in order to determine whether to recommend initiation of an Institutional Review and Investigation and/or refer this matter to another Research Committee. The RIO shall provide the results of his/her assessment to any Research Committee, Institutional Review and Investigation Committee, or other University personnel that is tasked with the handling of the Other Allegations.

D. Initiation of Institutional Review and Investigation Process and Appointment of Institutional Review and Investigation Committee: If the RIO determines that the initiation of an Institutional Review and Investigation is warranted, then the RIO will immediately notify the Administrative Official, and the Administrative Official shall work with the RIO to initiate the Institutional Review and Investigation process. The Administrative Official, in consultation with the RIO, shall, as soon as practical after the initiation of the Institutional Review and Investigation, appoint at least three members to form an Institutional Review and Investigation Committee and shall choose a committee Chair. The Institutional Review and Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial Conflicts of Interest with those involved with the Institutional Review and Investigation. Committee Members should include individuals with the appropriate expertise to evaluate the Evidence and issues related to the allegations, interview the Complainant and Respondent and key witnesses, and conduct the Institutional Review and Investigation. Some or all of the members of the Institutional Review and Investigation Committee may be selected from outside the University. Alternatively, the Administrative Official may appoint a standing committee that is authorized to conduct Institutional Review and Investigation and to add or use members when necessary to provide the necessary expertise and/or to eliminate Committee Members with Conflicts of Interest.

E. Securing Records and Taking Interim Administrative Actions/Sanctions: On or before the date on which the Respondent is notified of the initiation of the Institutional Review and Investigation, the RIO in consultation with the Administrative Official and must take all reasonable and practical steps to obtain custody of all original documents and other materials relevant to the allegations and sequester them in a secure manner. In the case of scientific instruments shared by a number of users, custody of copies of the data or evidence on such instruments may be maintained in lieu of the instruments provided that the copies are substantially equivalent to the data or evidence on the instruments. The Administrative Official also shall take any interim Administrative Actions/Sanctions that may be necessary or required in accordance with Section 7.8.01-C.4 of this Policy.

F. Notifications: The RIO will make the following notifications regarding the initiation of the Institutional Review and Investigation:

1. Notice to the Dean/Director of the Respondent’s unit in the event that the Chair of the unit is serving as the Administrative Official.

2. Notice to any sponsor of the Research in accordance with the notification provisions set forth in Section 7.8.01-C.5 and 7.8.01-C.6 of this Policy.

3. Notice to the Complainant and the Respondent at the time of or before beginning an Institutional Review and Investigation. The RIO must make a good faith attempt to notify the Complainant and the Respondent in writing of the initiation of the Institutional Review and Investigation and the identities of the members of the Institutional Review and Investigation Committee.
G. Objections Regarding Committee Members: The Complainant and the Respondent shall have ten days from the receipt of notice of the names of the committee members in which to provide the RIO with any written objection to the members of the Institutional Review and Investigation Committee. If no objection is received within this period, then any objection on the part of the Complainant or Respondent to the committee membership shall be considered waived. If an objection is made, then in order for it to be considered, it must be made in Good Faith and must set forth in sufficient detail a reasonable basis for the objection (e.g., Conflict of Interest). The Administrative Official shall consider the objection, and if s/he determines that the objection is made in Good Faith and is reasonable, a new member shall be appointed. If s/he determines that the objection is not made in Good Faith or is unreasonable, the membership of the committee shall remain the same.

H. Charge to the Institutional Review and Investigation Committee and First Meeting:

1. Charge to the Committee: The RIO shall prepare a charge for the Institutional Review and Investigation Committee that sets forth the following information:

   a. Identifies the Respondent.
   
   b. Describes the allegations and related issues identified during the RIO’s assessment of the allegations.
   
   c. Defines Regulation/Policy Violation and identifies pertinent regulations and policies that may have been violated.
   
   d. Advises the Institutional Review and Investigation Committee that it must thoroughly evaluate the Evidence and testimony of the Respondent, Complainant, and relevant witnesses in order to determine whether, based on a Preponderance of the Evidence, a Regulation/Policy Violation has occurred, and if so, to what extent, who was responsible, and how serious it was.
   
   e. Advises the Institutional Review and Investigation Committee that in order to determine that the Respondent committed a Regulation/Policy Violation it must find that a Preponderance of the Evidence establishes that the Respondent violated an applicable policy or regulation/law. If a violation is found, the Institutional Review and Investigation Committee also shall determine whether the violation was or was not committed intentionally, knowingly, or recklessly.
   
   f. Advises the Institutional Review and Investigation Committee that the Respondent has the burden of proving by a Preponderance of the Evidence any affirmative defenses raised.
   
   g. Informs the Institutional Review and Investigation Committee that it must take all reasonable steps to ensure the confidentiality of the proceedings.
   
   h. Informs the Institutional Review and Investigation Committee that if during the Institutional Review and Investigation, additional information becomes available that substantially changes the subject matter of the Institutional Review and Investigation or suggests additional Respondents, then the Institutional Review and Investigation Committee should notify the RIO, who in conjunction with the Administrative Official, will determine whether it is necessary to notify the Respondent of the new subject matter; and/or provide notice to additional Respondents; initiate other proceedings; and/or make referrals to other Research Committees.
   
   i. Informs the Institutional Review and Investigation Committee that it must prepare or direct the preparation of a written Institutional Review and Investigation Committee Report that meets the requirements set forth in Section 7.8.04-I.4 below.

2. First Meeting: At the Institutional Review and Investigation Committee’s first meeting, the RIO shall review the charge, discuss the allegations and any related issues, review the appropriate procedures for conducting the Institutional Review and Investigation, and answer any questions raised by the Institutional Review and Investigation Committee. The Institutional Review and Investigation Committee will be provided with a copy of this Policy and with copies of any pertinent laws, regulations or policies pertaining to the allegation of a Regulation/Policy Violation at issue. The RIO must be present during or available throughout the Institutional Review and Investigation to advise the Institutional Review and Investigation Committee as needed.

I. Conduct of the Institutional Review and Investigation:

1. Actions to be Taken: The Institutional Review and Investigation Committee should take the following
actions:

a. Interview the Respondent and the Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Institutional Review and Investigation, including witnesses identified by the Respondent and Complainant.

b. Use diligent efforts to ensure that the Institutional Review and Investigation is thorough and includes examination of all Research Records and Evidence relevant to reaching a decision on the merits of each allegation. The documents and materials to be reviewed should include, at least, the following: Research Records; data; proposals; publications; correspondence; pertinent policies, laws and regulations; and other relevant materials, including notes from any interviews conducted by the RIO.

c. Take reasonable steps to ensure an impartial and unbiased Institutional Review and Investigation to the maximum extent practical.

d. Pursue diligently all significant issues and leads discovered that are determined relevant to the Institutional Review and Investigation, including any evidence of additional instances of possible Regulation/Policy Violations and continue the Institutional Review and Investigation to completion;

e. Evaluate the Evidence and testimony and determine whether based on a Preponderance of the Evidence, a Regulation/Policy Violation occurred, and if so, what regulation or policy was violated, who was responsible, its seriousness, and whether it was violated intentionally, knowingly or recklessly.

f. Prepare and maintain notes and summaries regarding its conduct of the Institutional Review and Investigation to substantiate the Institutional Review and Investigation Committee’s findings.

2. Legal Counsel: All parties may retain legal counsel at their own expense, but legal counsel may not be present during the Institutional Review and Investigation Committee’s interviews or other proceedings. Legal counsel may interview witnesses who are employees of the University only through arrangement with the University’s Office of the General Counsel, and only with the consent of the witness.

3. Communications and Notifications During Institutional Review and Investigation: During the course of any Institutional Review and Investigation, the Institutional Review and Investigation Committee should keep the Administrative Official and the RIO apprised of any developments that disclose facts that may affect current or future sponsored Research for the Respondent, or that may be relevant to protecting the reputation of the University and/or the public interest. The RIO also shall provide notifications in accordance with Section 7.8.01-C.5 and III.C.6 above.

4. Institutional Review and Investigation Committee Report: The Institutional Review and Investigation Committee, in consultation with the RIO, is responsible for preparing a written draft report of the Institutional Review and Investigation that:

a. Describes the allegations of the Regulation/Policy Violation that were received.

b. Identifies the Respondent and the Complainant, unless the Complainant is anonymous.

c. Describes the Research that is involved, including any funding for the Research received from the University or other sponsors.

d. Describes any publications from the Research or that may be affected by the Research.

e. Describes the pertinent University policies and procedures, as well as any other laws, regulations or policies that apply.

f. Includes a statement of findings for each allegation. Each statement of findings must: (1) identify any Regulation/Policy Violation that occurred and what policy, regulation/law was violated; (2) identify whether the Regulation/Policy Violation was committed intentionally, knowingly, or recklessly; (3) summarize the facts and analysis supporting each statement of findings; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for
the Regulation/Policy Violation.

g. Includes a description of the recommended Administrative Actions/Sanctions. The nature of the Administrative Actions/Sanctions recommended/imposed shall depend on the severity of the misconduct/violation, and may range up to and include the dismissal of the Respondent. Administrative Actions/Sanctions may include, but are not limited to, any or all of the following: withdrawal of all pending abstracts and papers emanating from any Research tainted by the Regulation/Policy Violation; restitution of funds to the Research sponsor, as appropriate; notification of the editors of journals in which previous abstracts and papers were published; notification of institutions and sponsors with which the Respondent has been associated if there is reason to believe that the validity of previous Research might be questionable; and/or release of information about the incident to the press in cases in which health and safety issues or public funds were involved.

5. Comments on the Institutional Review and Investigation Committee Report: A draft of the Institutional Review and Investigation Committee Report must be provided to the Respondent for comment. The Respondent shall have thirty days from the date s/he received the draft report to provide comments to the Institutional Review and Investigation Committee. The Respondent’s comments must be considered and included as an attachment to the final report. A draft of the Institutional and Investigation Committee Report, or relevant portions of it, may be provided to the Complainant for comment. The Complainant shall have thirty days from the date s/he received the draft report to provide comments to the Investigation Committee. The Complainant’s comments must be considered and included as an attachment to the final report.

6. Transmittal and Implementation of the Final Report: The Institutional Review and Investigation Committee shall provide the final Institutional Review and Investigation Committee Report to the Administrative Official with a copy to the RIO. The report may be reviewed by the University’s counsel for legality and by the RIO for compliance with applicable policy. After receipt and review of the Institutional Review and Investigation Committee Report and any comments from Respondent or Complainant, the Administrative Official shall, in consultation with the RIO and other appropriate institutional officials, make a written Administrative Determination as to (a) whether to accept the Institutional Review and Investigation Committee’s findings; (b) whether to accept any recommendations put forward by the Institutional Review and Investigation Committee; and (c) whether to impose any new or additional requirements. In making this Administrative Determination, the Administrative Official shall give considerable weight to the findings and recommendations of the Institutional Review and Investigation Committee. In the event that the Administrative Official rejects the Institutional Review and Investigation Committee’s findings and/or recommendations, he/she shall set forth in the written Administrative Determination the reasons therefore, as well as the reasons for any new or additional requirements that the Administrative Official imposes. The Administrative Determination shall document any Administrative Actions/Sanctions that are to be imposed upon the Respondent, and the Administrative Determination document shall be added to the final Institutional Review and Investigation Committee Report. The Institutional Review and Investigation is finished when the Administrative Official completes this Administrative Determination. The Administrative Official shall notify the Respondent and the Complainant in writing of the Institutional Review and Investigation Committee’s findings and the Administrative Determination and provide the RIO and Respondent with copies of the Administrative Determination and the final Institutional Review and Investigation Committee Report. The Administrative Official also shall notify the appropriate university officials of the Institutional Review and Investigation Committee’s findings and the Administrative Determination.

Based on the final report and the Administrative Determination, the RIO will determine whether sponsors, government agencies, law enforcement agencies, professional societies, professional licensing boards, editors of journals, 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 set forth in Section 7.8.01-C.4 above.

7. Appeal: The Respondent shall have the right to appeal a finding of a Policy/Regulation Violation to the Provost or the appropriate Vice President in charge of Respondent’s unit within ten days after the Administrative Official provides the Respondent with the final Institutional Review and Investigation Committee Report and the Administrative Official’s written determination. The only grounds for appeal are procedural error, or substantive new Evidence in favor of the Respondent, that would necessitate the reversal of the decision. The appeal must be in writing and must specifically enumerate the grounds for appeal and provide documentation or affidavits of any substantive new evidence for consideration. If no appeal is received by the end of the ten day period, the Respondent shall be deemed to have waived any appeal rights. If an appeal is received in a timely fashion, the appropriate Vice President or Provost will appoint an Appeals Committee consisting of three individuals who have sufficient expertise to review the appeal and who do not have any Conflict of Interest with regard to the Respondent or the matter for review. Members of the Institutional Review and Investigation Committee shall not be eligible to serve on the Appeals Committee. The Appeals Committee shall have thirty days within which to review the record of the Inquiry and Investigation proceedings, and the Respondent’s substantive new Evidence (if any), and issue an Appeals Report to the Provost or Vice President that provides as follows:

a. If the Appeals Committee determines that the Institutional Review and Investigation did not have such procedural errors, and/or there exists no substantive new Evidence
that could justify reversing the decision of the Institutional Review and Investigation Committee, then the appeal shall be denied.

b. If the Appeals Committee determines that there were procedural errors in the Institutional Review and Investigation, or that substantive new Evidence exists that could justify reversing the decision of the Institutional Review and Investigation, then the Appeals Committee may grant the appeal and recommend a new Institutional Review and Investigation by the same or a different Institutional Review and Investigation Committee.

8. Time Limit for Institutional Review and Investigation: By no later than ninety days after the date of the Institutional Review and Investigation Committee’s initial meeting, the Institutional Review and Investigation Committee should conduct its Institutional Review and Investigation and submit its final report to the Administrative Official and the Administrative Official shall issue the Administrative Determination. The Administrative Official shall have thirty days within which to provide the Respondent with the final report and the Administrative Determination. The Respondent shall then have ten days from receipt of the final Institutional Review and Investigation Committee Report and Administrative Determination within which to appeal any decision. The Appeals Committee shall have thirty days from the receipt of an appeal in which to grant or deny the appeal. If the appeal is denied, the final Institutional Review and Investigation Committee Report, Administrative Determination, and notice of the denial of the appeal, must be provided to the Respondent within 180 days after the initial meeting of the Institutional Review and Investigation Committee. Notwithstanding anything to the contrary herein, any of the foregoing periods may be extended for reasonable cause by the Administrative Official in consultation with the RIO, upon written application for an extension by the Institutional Review and Investigation Committee.

9. Record-Keeping Requirements: The RIO shall keep all records related to the Institutional Review and Investigation in a secure manner for at least three years after the date on which the Institutional Review and Investigation, and any subsequent appeal concludes. All records shall be made available upon request to governmental agencies as may be required by law, and in accordance with, all applicable Governmental Requirements.

10. Early Termination of an Institutional Review and Investigation: If the Institutional Review and Investigation Committee determines that circumstances (e.g., full retraction of allegations, admission of Respondent) make it appropriate to terminate the Institutional Review and Investigation early, then the Institutional Review and Investigation Committee may document the reasons for an early termination in a report and submit the report to the Administrative Official for consideration and a decision as to whether the Institutional Review and Investigation may be terminated. The resignation or termination of a Respondent prior to the conclusion of an Institutional Review and Investigation shall not in and of itself be sufficient justification to support the early termination of an Institutional Review and Investigation.

11. Restoration of Reputations: In the event that the Institutional Review and Investigation Committee determines that there was no Regulation/Policy Violation this determination is accepted by the Administrative Official, and no other violations have occurred, then the University will diligently make appropriate efforts to restore the reputation of the Respondent and to protect the position and reputation of any Complainant who brought allegations in good faith.

Definitions

Throughout this Policy, Defined Terms are shown as italicized, capitalized terms. These terms and their meanings are set forth below:

Administrative Official means the institutional official who makes final determinations with regard to Allegations of Research Misconduct Regarding Federally-Sponsored Research and/or Other Allegations as well as any institutional Administrative Actions/Sanctions to be taken.

Administrative Actions/Sanctions means any actions taken by Emory University on its own initiative or in consultation with appropriate governmental officials at any time during or after an Research Misconduct Proceeding, Institutional Review and Investigation or other proceeding under this Policy in order to protect the health and safety of Research subjects; to protect the funds or resources of sponsors; to protect the University’s reputation and/or academic integrity; to protect the integrity of the Research process; to comply with any applicable governmental laws, regulations or policies; and/or to comply with any applicable Emory University policies or contractual obligations.

Administrative Determination means the action taken by an Administrative Official, in consultation with the RIO and other appropriate institutional officials, with regard to (a) accepting or rejecting the findings of an Inquiry Committee, Investigation Committee, or Institutional Review and Investigation Committee; (b) accepting or rejecting the recommendations of the aforesaid committees; and/or (c) imposing any new or additional requirements.
**Allegation of Research Misconduct** means a disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an official of the Institution or a federal government official, who in turn notifies an official of the Institution.

**Appeals Committee**: A committee that is established by the Institution to consider an appeal of the decision of an Investigation Committee or of an Institutional Review and Investigation Committee.

**Committee Member**: A member of a committee that the Institution impanels: (a) for the purpose of conducting an Inquiry or Investigation into an Allegation of Research Misconduct under Section 7.8.03 of this Policy; or (b) for the purpose of conducting an Institutional Review and Investigation into Other Allegations under Section 7.8.04 of the Policy; or (c) for the purpose of considering an appeal of the decision of an Investigation Committee or of an Institutional Review and Investigation Committee.

**Complainant** means a person who in Good Faith makes an Allegation of Research Misconduct or Other Allegations. A Complainant may make allegations anonymously and request that anonymity be preserved throughout the proceeding; however, the RIO and any committee appointed under this Policy may take this fact into consideration in determining whether the allegations are substantive and/or brought in Good Faith.

**Conflict of Interest** means the real or apparent interference of one person’s or entity’s interests with the interests of another person or entity, where potential bias may occur due to prior existing personal or professional relationships.

**Evidence** means any document, tangible item, or testimony offered or obtained during a Research Misconduct Proceeding or other proceeding under this Policy that tends to prove or disprove the existence of an alleged fact.

**Fabrication** means making up of Research data or results and recording or reporting them.

**Falsification** means manipulating Research materials, equipment, or processes, or changing or omitting data or results such that the Research is not accurately represented in the Research Records.

**Federally-Sponsored Research** means Research that is funded by an entity or component of the United States federal government, which includes but is not limited to:

a. Any type of Research receiving funding from a federal source, including Research in science, medicine, social sciences and other academic areas.

b. Research receiving NSF Support.

c. Research receiving PHS Support, including --

i. Research projects that are supported by, or for which an application for support has been submitted to PHS and/or agencies that administer funds made available under the PHS Act (e.g., National Institutes of Health).

ii. Biomedical or behavioral Research, Research training or activities related to that Research or Research training (e.g., operation of tissue and data banks and dissemination of Research information).

iii. Applications or proposals for PHS Support for biomedical or behavioral Research, Research training or activities related to that Research or Research training.

iv. Plagiarism of Research Records produced in the course of Research, Research training or activities related to that Research or Research training that received PHS Support; and

v. Any Research proposed, performed, reviewed or reported, or any Research Records generated from that Research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement other form of PHS Support.

**Good Faith** as applied to a Complainant or witness means having a belief in the truth of one’s allegation or testimony that a reasonable person in the Complainant’s or witness’s position would have, based on the information known to the Complainant or witness at the time. An allegation is not made, and cooperation with a Research Misconduct Proceeding, or other proceeding under this Policy, is not undertaken in Good Faith if it is made/undertaken with knowing or reckless disregard for information that would negate the allegation or testimony. Good Faith as applied to a Committee Member means cooperating with the purpose of helping an Institution meet its responsibilities under this Policy and, as applicable, under 42 CFR Part 93 or other applicable federal regulations. A Committee Member does not act in Good Faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial Conflicts of Interest with those involved in the Research Misconduct Proceeding or other proceedings under this Policy.

**Governmental Requirements** is a collective reference to all United States federal laws, regulations and policies that apply to specific Research.
**Health and Human Services or HHS** means the United States Department of Health and Human Services.

**Inquiry** means preliminary information-gathering and preliminary fact-finding to determine whether an Allegation of Research Misconduct has substance and warrants an Investigation in accordance with the criteria and procedures set forth in 42 CFR §§93.307-93.309 in the case of Research receiving PHS Support, or other applicable federal regulations, including 45 CFR §§ 689.1-.10 in the case of Research receiving NSF Support.

**Inquiry Committee** means the group of individuals appointed to conduct an Inquiry under this Policy.

**Inquiry Committee Report** means the written report issued by the Inquiry Committee to the Administrative Official and the RIO at the end of the Inquiry Committee’s proceedings.

**Institution** means any individual or entity that applies for or receives PHS, NSF or other federal government support for any activity or program that involves the conduct of Research, including activities related to that Research, or Research training. This term includes, but is not limited to, colleges and universities. For purposes of this Policy, Emory University shall be considered to be the Institution.

**Institutional Member** means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an Institution. Institutional Members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

**Institutional Review and Investigation** means the information-gathering, fact-finding, evaluation and determination process conducted by an Institutional Review and Investigation Committee in order to make findings as to whether or not there has been an occurrence of (a) Research Misconduct; or (b) a Regulation/Policy Violation.

**Institutional Review and Investigation Committee** means the group of individuals appointed to conduct an Institutional Review and Investigation under this Policy.

**Institutional Review and Investigation Committee Report** means the written report issued by the Institutional Review and Investigation Committee to the Administrative Official and the RIO at the end of the Committee’s proceedings.

**Investigation** means the formal development of a factual record and the examination of that record leading to a decision as to whether or not there has been Research Misconduct, as well as making recommendations for other appropriate actions, including Administrative Actions/Sanctions.

**Investigation Committee** means the group of individuals appointed to conduct an Investigation under this Policy.

**Investigation Committee Report** means the written report issued by the Investigation Committee to the Administrative Official and the RIO at the end of the Investigation Committee’s proceedings.

**National Science Foundation or NSF** means the independent federal agency founded to promote the progress of science which has promulgated the regulations set forth at 45 CFR Chapter VI, Parts 601 to 690, including the policies at Part 689 governing matters concerning Research Misconduct as it pertains to Research receiving NSF Support.

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

**NSF Office of Inspector General** or the **NSF OIG** means the office within NSF that oversees investigations of Research Misconduct and conducts NSF inquiries or investigations into such allegations.

**NSF Support** means NSF funding (or applications or proposals therefor) for any type of Research, or related training or education.

**Office of Research Integrity or ORI** means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to activities receiving PHS Support.

**Other Allegations** means any disclosure or communication of possible Regulation/Policy Violations to any official of the Institution or to any governmental official who, in turn, discloses or communicates the information to an official of the Institution.

**PHS Support** means PHS funding, or applications or proposals therefor, for biomedical or behavioral
Research, biomedical or behavioral Research training, or activities related to that Research or training, that may be provided through PHS; 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.

Plagiarism means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

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.

Public Health Service or PHS means the units within the Department of Health and Human Services including 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, Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

Records of Research Misconduct Proceedings means:
   a. Any Research Records and Evidence secured for the Research Misconduct Proceeding pursuant to Section 7.8.03 of this policy, 42 CFR §§93.305, 93.307(b) and 93.310(d), and any other applicable federal regulations, except to the extent the RIO determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained;
   b. Any documentation of the determination of irrelevant or duplicate records;
   c. Any Inquiry Committee Report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate;
   d. Any Investigation Committee Report and all records (other than drafts of the report) in support of the report, including the recordings or any transcripts of each interview conducted; and
   e. The complete record of any appeal within the Institution from the finding of Research Misconduct.

Records of Proceedings means any reports and supporting documentation related to a proceeding conducted under this Policy other than a Research Misconduct Proceeding.

Regulation/Policy Violation means a material failure to comply with any applicable federal, state or local law, regulation or policy or with any applicable Emory University policy or requirement that applies to Research or the conduct or funding of Research that does not fall within the definition of Research Misconduct. Regulation/Policy Violations include, but are not limited to, the following acts: (i) material failure to comply with federal, state, or local laws, regulations and policies and/or Emory policies, procedures, and requirements regarding Research; (ii) failure to obtain proper review and approval by the responsible Emory Research review/oversight committee or committees (e.g., IRB, Institutional Animal Care and Use Committee, Radiation Safety Committee, Institutional Health and Biosafety Committee, all such committees collectively referred to herein as “Research Committees”); (iii) the failure to follow policies or requirements established by or recommendations made by Emory Research Committees; (iv) failure to meet other material legal requirements governing Research; (v) failure to notify Emory authorities when it becomes apparent that Research Misconduct or a Regulation/Policy Violation probably has occurred; and (vi) failure to cooperate in proceedings under this Policy or other applicable policies, procedures or regulations. For purposes of this Policy, a Regulation/Policy Violation does not include Allegations of Research Misconduct or findings of Research Misconduct.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) including, but not limited to 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. With regard to Research funded by the NSF, Research includes proposals submitted to NSF in all fields of science, engineering, mathematics, and education and results from such proposals.

Research Committees: Those committees at Emory University that are responsible for review and oversight of Research, including, but not limited to, the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Radiation Safety Committee, Institutional Health and Biosafety Committee (IHBC).

Research Integrity Officer (RIO) means the Institution’s official responsible for:
   a. Assessing Allegations of Research Misconduct to determine whether they fall within the definition of Research Misconduct; are covered by 42 CFR Part 93 if the Research has received PHS Support; are covered by 45 CFR § 689.1 to .10, if the Research has received
NSF Support; and warrant an Inquiry on the basis that the allegations are sufficiently credible and specific so that the potential Evidence of Research Misconduct may be identified;

b. Assessing Other Allegations to determine if they fall within the scope of this Policy, and if so, determining whether they come under the procedures set forth in Section 7.8.03 or Section 7.8.04 of this Policy;

c. Overseeing the administration of Inquiries and Investigations; and overseeing the administration of an Institutional Review and Investigation; and

d. Carrying out other responsibilities assigned to the RIO in this Policy.

Research Misconduct means Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing Research; submitting proposals for Research; or in reporting Research results. It does not include honest error or honest differences in interpretations or judgments of data.

Research Misconduct Proceeding means any actions related to Allegations of Research Misconduct taken under this Policy, including but not limited to, allegation assessments, Inquiries and Investigations.

Research Records means those records of data or results that embody the facts resulting from scientific inquiry, including but not limited to, Research proposals, laboratory records (physical and electronic), progress reports, abstracts, theses, oral presentations, internal reports, journal articles, as well as these and any other documents and materials that (a) a Respondent provides to HHS, NSF, other federal agencies, or institutional officials in the course of a Research Misconduct Proceeding; or (b) a Respondent provides to officials of the Institution or appropriate governmental officials during the conduct of any other proceeding conducted under this Policy.

Respondent means the person against whom an Allegation of Research Misconduct or Other Allegation is directed or who is the subject of a Research Misconduct Proceeding or other proceeding conducted under this Policy.

Retaliation means an adverse action taken against a Complainant, witness, or Committee Member by an Institution or one of its members in response to:

- Good Faith Allegations of Research Misconduct;
- Other Allegations made in Good Faith; or
- Good Faith cooperation with a Research Misconduct Proceeding or any other proceeding conducted under this Policy.

Secretary of HHS means the Secretary of HHS or any other officer or employee of HHS to whom the Secretary delegates authority.

Related Links

- Current Version of This Policy: http://policies.emory.edu/7.8

Contact Information

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<tr>
<th>Subject</th>
<th>Contact</th>
<th>Phone</th>
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</thead>
<tbody>
<tr>
<td>Clarification of Policy</td>
<td>Office of Research Compliance</td>
<td>404-727-3827</td>
<td><a href="mailto:kwest02@emory.edu">kwest02@emory.edu</a></td>
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Revision History

Emory University policies are subject to change at any time. If you are reading this policy in paper or PDF format, you are strongly encouraged to visit policies.emory.edu to ensure that you are relying on the current version.