SUBJECT:	Effective Date:	Policy Number:
Research Misconduct	11/20/2013	10.1.1
	Supersedes:	Page Of
	05/02/2012 12/22/2010 06/23/2010 03/27/2009	

FAU received the allegation. Authorship or collaboration disputes involving students should be directed to the dean of undergraduate or graduate studies, as applicable.

While this policy is based upon the model policy of the US Public Health Service (PHS) and has been crafted in close accordance with PHS Regulations (specifically Code of Federal Regulations Title 42, Part 93), it is intended to be FAU's institutional policy applicable to all research conducted by any FAU institutional member, paid or unpaid, regardless of the location of the research or the source of the funding. This policy is intended both to carry FAU's responsibilities under the various agency policies on Research Misconduct and to set out a process for the resolution of any and all instances of research misconduct.

POLICY STATEMENT:

Florida Atlantic University ("University" or "FAU") requires ethical conduct in all teaching and research. Collegiality, respect, and trust among faculty members, students, and staff are essential to FAU's success. All allegations of research misconduct must be resolved promptly and equitably using procedures that safeguard the rights of all faculty, staff and students concerned. This policy is adopted by FAU in compliance and consistent with laws, rules and regulations of the United States, the State of Florida, the Florida Board of Governors, the Florida Atlantic University Board of Trustees, and, for those employees included in the bargaining unit, the FAU Board of Trustees/United Faculty of Florida Collective Bargaining Agreement. It will be updated administratively in accordance with changes in those laws, rules, and regulations.

OVERVIEW

As noted, this FAU Research Misconduct policy is motivated by and flows from the model policy of the US Public Health Service (Department of Health and Human Services), which was developed as a link among misconduct policies of several federal agencies. Given the serious nature of the subject of this policy and its quasi-legal implications, this document involves a high level of detail and specificity. In addition, various terms have specific definitions; see Appendix B (p. 22).

Notwithstanding its basis in the PHS model and the definitions in Appendix B (which follow federal language), this policy is a Florida Atlantic University document, and it applies to all research at FAU regardless of funding source. Because the procedures discussed below are complicated, the following table provides a step-by-step overview of the time line with references to the sections of this document. For completeness here, the four major steps in the process are subdivided into their several components. The table, however, is not meant to be comprehensive concerning the details of the procedure or its rationale.

In brief, (i) *allegations* of misconduct are (ii) *assessed* by the Research Integrity Officer; if

Step	Procedures Section	Event	**Deadline** (in calendar days)
(1)	A.2	Report of misconduct allegation	Beginning of process
(2)	B.1	Assessment by Research Integrity Officer	Within 5 days of (1)
(3)	B.2/4	Formation of Inquiry Committee (if warranted)	Within 10 days of (1)
(4)	B.4	Respondent objections to committee make-up	Within 5 days of (3)
(5)	B.7 / C	Inquiry Report	Within 20 days of (1)
(6)	C.2	Respondent comments	Within 10 days of (5)
(7)	C.3	Deciding Officer's decision to investigate (or not)	Within 5 days of (6)
(8)	D.1	Investigation begins (if appropriate)	Within 30 days of (7)
(9)	D.3	Formation of Investigation Committee	Within 10 days of (8)
(10)	D.3	Respondent objections to committee make-up	Within 5 days of (9)
(11)	D.6	Investigation Report	Within 80 days of (8)
(12)	E.2	Respondent comments	Within 15 days of (11)
(13)	E.3	Deciding Official decision	Within 5 days of (12)

Appendix A (p. 16) of this document outlines in detail the responsibilities of the Research

Cooperation with Research Misconduct Proceedings

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

Confidentiality

misconduct proceeding, notify the Cognizant Agency immediately if he/she has reason to believe that any of the following conditions exist:

Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
HHS resources or interests are threatened;
Research activities should be suspended;
There is a reasonable indication of possible violations of civil or criminal law;

Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph B.3 below.

B.2 Initiation and Purpose of the Inquiry

States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of this policy; and, (2) the allegation may have substance, based on the committee's review during the inquiry.

Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy.

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

B.6 Inquiry Process

The inquiry committee will normally interview the Complainant, the Respondent, and key witnesses, as well as examine relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with the Cognizant Agency to determine the next steps that should be taken. See Section C.3 below.

B.7 Time for Completion

The inquiry, including preparation of the draft inquiry report and the recommendation of the RIO on whether an investigation is warranted, must be completed within 20 calendar days of receipt of allegation, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 20-day period. The Respondent should be notified of the extension.

C The Inquiry Report

C.1 Elements of the final Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the Respondent; (2) a description of the allegations of research misconduct; (3) the funding source, including, for example, grant numbers, grant applications, contracts and publications listing the support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the Respondent or Complainant. The inquiry report should also include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

C.2 Notification to the Respondent and Opportunity to Comment

The RIO shall notify the Respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or reference to the Cognizant Agency's regulations and the FAU policies and procedures on research misconduct.

that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

D.2 Notifying the Cognizant Agency and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the Cognizant Agency Director of the decision to begin the investigation and provide the Cognizant Agency a copy of the inquiry report; and (2) notify the Respondent in writing of the allegations to be investigated. The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct investigation that were not previously sequestered during the inquiry. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

D.3 Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the beginning of the investigation or as soon thereafter as practical. The investigation committee must consist of faculty who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution. The RIO will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Respondent has 5 calendar days to file an objection. The DO will make the final determination of whether a conflict exists.

D.4 Charge to the Committee and the First Meeting

<u>D.4.1 Charge to the Committee</u>

The RIO will define the subject matter of the investigation in a written charge to the committee that:

Describes the allegations and related issues identified during the inquiry;
Identifies the Respondent;

Informs the committee that it must conduct the investigation as prescribed in paragraph D.5 below;
Defines research misconduct;
Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
Informs the 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, as defined in this policy, occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and
Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy.

D.4.2 First Meeting

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

D.5 Investigation Process

The investigation committee and the RIO must:

Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

D.6 Time for Completion

The investigation is to be completed within 80 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the Cognizant Agency. However, if the RIO determines that the investigation will not be completed within this 80-day period, he/she will submit to the Cognizant

except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to the Cognizant Agency.

G Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include, but are not limited to:

Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
Restitution of funds to the grantor agency as appropriate;
Dismissal of a student from a program, College or the University;
Revocation of a degree from a former student who has received a degree from FAU, ;
Other action consistent with University policy appropriate to the misconduct. This includes action by the DO acting as University Provost or referral of the matter for further administrative action by the University and if a student has been involved, application of the Student Code of Conduct.

H Other Considerations

H.1 Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's FAU affiliation, by resignation, withdrawal or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the FAU's responsibilities.

If the Respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

H.2 Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including the Cognizant Agency concurrence, the RIO will, at the request of the Respondent, undertake all reasonable and

personnel file. Any institutional actions to restore the Respondent's reputation should first be approved by the DO.

H.3 Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or the Cognizant Agency determines that research misconduct occurred, the RIO will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding, including students involved in the process. The DO will determine, after consulting with the RIO, and with the Complainant,

Sends to the Cognizant Agency with the annual report such other aggregated information as it may prescribe on the institution's research misconduct proceedings and the institution's compliance;

Notifies the Cognizant Agency immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, federal resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed;

Provides the Cognizant Agency with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made;

Notifies the Cognizant Agency of the decision to begin an investigation on or before the date the investigation begins;

Within 120 days of beginning an investigation, or such additional days as may be granted by the Cognizant Agency, provides the Cognizant Agency with the investigation report, a statement of whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent;

Seeks in advance the Cognizant Agency’s approval if the institution plans to close a case at the inquiry or investigation on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage;

Cooperates fully with the Cognizant Agency during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

3.0 Research Misconduct Proceeding

3.1 General

The RIO is responsible for:

Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner;

Taking all reasonable and practical steps to ensure the cooperation of Respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence;

Providing confidentiality to those involved in the research misconduct proceeding;

Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding;

Keeping the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith Complainants, witnesses, and committee members and to counter potential or actual retaliation against them by Respondents or other institutional members;

Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made;

Assisting the DO in implementing his/her decision to take administrative action against any Complainant, witness, or committee member determined by the DO not to have acted in good faith;

Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical;

Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures;

Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise;

Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews;

Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in this policy;

Determining whether circumstances clearly warrant a period longer than that specified in paragraph B.7 of this policy to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the period specified in the policy on the record of the research misconduct proceeding;

Assisting the inquiry committee in preparing a draft inquiry report, sending the Respondent a copy of the draft report for comment within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent, and ensuring that the comments are attached to the final inquiry report;

Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an investigation is warranted;

Within 30 days of a DO decision that an investigation is warranted, providing the Cognizant Agency with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision;

Notifying the Respondent whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to Cognizant Agency regulations and the institution's research misconduct policies and procedures;

Providing to the Cognizant Agency, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents , and the charges to be considered in the investigation;

If the DO decides that an investigation is not warranted, securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by the Cognizant Agency of the reasons why an investigation was not conducted.

3.4 Investigation

The RIO is responsible for:

Initiating the investigation within 30 calendar days after the determination by the DO that an investigation is warranted;

On or before the date on which the investigation begins: (1) notifying the Cognizant Agency of the decision to begin the investigation and providing the Cognizant Agency a copy of the inquiry report; and (2) notifying the Respondent in writing of the allegations to be investigated;

Prior to notifying Respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry;

In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical;

Preparing a charge for the investigation committee in accordance with the institution's policies and procedures;

Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and the Cognizant Agency's regulations;

Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews;

Being available or present throughout the investigation to advise the committee as needed;

Acting, on behalf of the institution, as the responsible party for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion;

Upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to the Cognizant Agency), submitting a request to the Cognizant Agency for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with the Cognizant Agency;

Assisting the investigation committee in preparing a draft investigation report that meets the requirements of the Cognizant Agency's regulations and the institution's policies and procedures, sending the Respondent a copy of the draft report for his/her comment within 15 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent, and ensuring that the comments are included and considered in the final investigation report;

Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency;

Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee;

Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to the Cognizant Agency within the time period for completing the investigation, a copy s hat 1.1803 -1.12475 TD43001 Tcalttsveststatedi

APPENDIX B

Definitions

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or Cognizant Agency official. The written allegation(s) will be date stamped. In the event that, the allegation is made verbally, the RIO or designee shall promptly reduce it to writing and date stamp the allegation as received on that date. In the event the allegation is received electronically, the RIO, or designee, will date stamp the document immediately upon receipt.

Cognizant agency, is the organization associated with the funding source for the research activity in question that is responsible for matters involving research misconduct. For example, the Cognizant Agency for research funded by the National Institutes of Health is the HHS Office of Research Integrity.

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

Days are calendar days, not business days.

Deciding Official (DO) is the University Provost, or designee. The DO is the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A Deciding Official's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Good faith, as applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member, faculty, or student means cooperating with the purpose of helping an institution meet its responsibilities. 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.

HHS means the United States Department of Health and Human Services.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures herein.

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 sub-awardees, and their employees.

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

Office of Research Integrity (the Cognizant Agency for HHS) means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

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

Records of research misconduct proceedings means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and Cognizant Agency regulations, except to the extent the Research Integrity Officer determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.

Research Integrity Officer (RIO) means the institutional official responsible for: (1) assessing allegations of research misconduct to determine whether they fall within the definition of research misconduct, are covered by Cognizant Agency regulations, or the allegation is sufficiently specific so that potential evidence of research misconduct may be identified; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. In the event the RIO has a conflict of interest, then the RIO will refer the matter to the Inquiry Committee and all other duties of RIO will be referred to the chair of the Inquiry Committee.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.