Tulane University Policies and Procedures for Responding to Allegations of Research Misconduct

RESPONSIBLE UNIVERSITY OFFICIAL: Research Integrity Officer ("RIO")
RESPONSIBLE OFFICE: Vice President for Research
COORDINATING DEPARTMENTS: Research Compliance Office (RCO)

ISSUED DATE: March 7, 2022 **EFFECTIVE DATE:** March 7, 2022
LAST REVIEWED DATE: April 2, 2024 **NEXT REVIEW DATE:** March 2, 2025

WHO NEEDS TO KNOW THIS POLICY: All persons who participate in, are involved in, and/or conduct research under the auspices of Tulane

WEBSITE ADDRESS FOR THIS POLICY: https://research.tulane.edu/compliance/policies-procedures

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I. Principles

Tulane University (Tulane or the university) cultivates an environment that focuses on the generation of new knowledge through Research. Tulane is a Research university, and it is committed to the highest standards of integrity in Research. Public trust in the integrity of Research is essential, and maintaining high standards is an important university responsibility. Everyone involved in Research shares the responsibility for preserving its integrity by encouraging the highest ethical principles and by holding members of the Research community accountable. Misconduct damages the integrity of the Research enterprise, harms the reputations of all researchers, and undermines public trust. The university does not tolerate Research Misconduct and uses this Policy to deal effectively and expeditiously with Allegations or Evidence of Research Misconduct.[1]

II. Scope

A. This Policy applies to all Allegations of Research Misconduct related to all Research conducted at Tulane. Specifically, this Policy applies to:
   1. funded Research, regardless of the funder;
   2. unfunded Research;
   3. Research that is proposed, performed, reviewed or reported; and/or
   4. the Research Record generated from Research.

   This Policy applies regardless of whether a funding application or proposal results in a grant, contract, cooperative agreement or other form of support.[2]

B. Federally Sponsored Research is subject to specific requirements. Tulane intends this Policy to comply with those specific requirements, in particular the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93) and the National Science Foundation's (NSF) Policies on Research Misconduct (45 CFR Part 689). When Tulane's

Policy is applied to Research that is sponsored by a federal entity whose policy differs from the provisions within this Policy, then that federal entity's policy governs.

C. This Policy applies to all persons who participate in Research under the auspices of Tulane including but not limited to faculty, visiting scholars, staff and students.

D. This Policy operates in conjunction with existing Tulane policies for employment and academic conduct. Recommendations for discipline resulting from proceedings conducted pursuant to this Policy will be administered according to Tulane's Faculty Handbook, Tulane's Staff Handbook, and/or Tulane's student code of conduct.

E. This Policy applies to Allegations of Research Misconduct occurring within six years of the date that Tulane or the funder received the Allegation, subject to the following exceptions. The six-year time limitation does not apply if:

   1. the Respondent continues or renews an incident of Alleged Research Misconduct that occurred before the six-year time limitation and does so through the citation, republication or other use for the potential benefit of the Respondent;[3] or
   2. Tulane or a federal government sponsor of research determines that the alleged Research Misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.[4]

F. The university may modify the application of this Policy as appropriate based on the facts and circumstances of a particular matter.

G. Proceedings pursuant to this Policy do not preclude additional proceedings involving other Tulane units or committees using other policies and regulations.

III. Institutional Commitments

A. Tulane makes the following commitments regarding its handling of Allegations of Research Misconduct. The university:

   1. operates under the presumption that a person accused of Research Misconduct is innocent unless and until acts of Research Misconduct are proved through the processes provided in this Policy;

2. provides an environment that promotes ethical Research. The university expects all Research to be conducted in compliance with all applicable regulations and policies. The university does not tolerate Research Misconduct and deals promptly with Allegations and/or Evidence of possible Research Misconduct;
3. responds to Allegations of Research Misconduct thoroughly, competently, objectively and fairly;
4. takes all reasonable and practical steps to exclude from participation in a Research Misconduct Proceeding those individuals who have unresolved personal, professional and/or financial Conflicts of Interests with Complainant, Respondent and/or Witnesses;
5. takes all reasonable and practical steps to protect the Research process during a Research Misconduct Proceeding;
6. takes all reasonable and practical steps to protect the positions and reputations of Good Faith Complainant, Witnesses and Committee Members and protect them from Retaliation (*see* Protecting Against Retaliation, below);
7. treats all persons with fairness while conducting a Research Misconduct Proceeding;
8. conducts a Research Misconduct Proceeding in a way that is sensitive to the reputation and vulnerability of those involved. When an Allegation is not substantiated, the university will make diligent efforts to restore the reputation of the person against whom the Allegation was made, the Complainant who made a Good Faith Allegation, and all who participated in the Research Misconduct Proceeding in Good Faith;
9. takes all reasonable and practical steps to preserve the highest attainable degree of Confidentiality that is compatible with an effective and efficient Research Misconduct Proceeding. Strict Confidentiality will be maintained for all information gathered in the Research Misconduct Proceeding. This may include seeking assurances of the confidential treatment of information, such as through the use of Confidentiality agreements. If Confidentiality is breached, the university will take reasonable steps to minimize damage to reputations that may result from inaccurate information;

10. takes all reasonable and practical steps to ensure the cooperation of Respondent and Institutional Members with a Research Misconduct Proceeding including but not limited to providing information, Research Records and Evidence;
11. resolves Allegations of Research Misconduct as expeditiously as possible; and
12. discharges responsibilities internally and externally, including to the public, the funders of Federally Sponsored Research, the literature, and the academic community to the extent appropriate and allowable.[5]

IV. Definitions and Concepts

The meanings of terms used in this Policy are explained below. Throughout this Policy, singular and plural terms are interchangeable. Defined terms are capitalized throughout this Policy.

A. Administrative Action means steps taken by the university on its own or in consultation with appropriate government officials at any time during or after a Research Misconduct Proceeding to protect health and safety; to protect funds and/or resources of sponsors; to protect the university' reputation and/or academic integrity; to protect the integrity of the Research process; to comply with applicable government regulations and/or policies; and/or to comply with applicable university policies and/or contractual obligations.[6]

B. 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 Tulane or a sponsoring entity, which notifies the university.[7]

C. Committee Member means a member of a committee that Tulane appoints for the purpose of conducting an Inquiry or Investigation into an Allegation of Research Misconduct pursuant to this Policy.

D. Complainant means a person who in Good Faith makes an Allegation of Research Misconduct.[8] A Complainant may make an Allegation anonymously and request that anonymity be preserved throughout the proceeding.

E. *Confidentiality* means that the disclosure of the identity of a Respondent and Complainant in a Research Misconduct Proceeding is limited to the extent possible to

those who need to know, consistent with a thorough, competent, objective and fair Research Misconduct Proceeding, and as allowed by law. For PHS supported Research, the university must disclose the identity of a Respondent and Complainant to the U.S. Department of Health and Human Service's Office of Research Integrity (ORI) when it reviews the Research Misconduct Proceeding.[9] Except as otherwise allowed by law, Confidentiality must be maintained for records or Evidence from which Research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a Research Misconduct Proceeding.[10]

F. *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 (or may appear to occur) due to prior or existing personal or professional relationships.

G. *Deciding Official* means the Tulane Senior Vice President for Academic Affairs and Provost who makes the final determination on Allegations of Research Misconduct for the university and imposes Administrative Action.

H. *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.[11]

I. *Evidentiary Standard* means the rules and principles used to make a decision regarding an Allegation of Research Misconduct. The following Evidentiary Standards apply to this Policy.

   1. *Standard of Proof* means the amount of Evidence needed to prove an Allegation of Research Misconduct. The Standard of Proof for an Allegation of Research Misconduct is a Preponderance of the Evidence. A 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.[12] Rules of Evidence applicable in courts of law do not apply.
   2. *Burden of Proof* means the obligation to prove an Allegation of Research Misconduct. The following Burdens of Proof apply.

i. The university has the Burden of Proof for an Allegation of Research Misconduct.[13]

ii. The Respondent has the burden of going forward with and the burden of proving, by a Preponderance of the Evidence, any and all affirmative defenses raised. In determining whether the university has carried the Burden of Proof, the finder of fact must give due consideration to admissible, credible Evidence of honest error or difference of opinion presented by the Respondent.[14]

iii. The Respondent has the burden of going forward with and proving by a Preponderance of the Evidence any mitigating factors that are relevant to a decision to impose Administrative Action following a Research Misconduct Proceeding.[15]

J. *Fabrication* means making up research data or results and recording or reporting them.[16]

K. *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 Record.[17]

L. *Federally Sponsored Research* means Research that is applied for and/or funded by an entity or component of the United States government, including but not limited to the PHS and NSF.

M. *Good Faith* 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 at the time. An Allegation of Research Misconduct or cooperation with a Research Misconduct Proceeding is not in Good Faith if it is done with knowing or reckless disregard for information that would negate the Allegation or testimony. Good Faith as applied to a Committee Member means impartially cooperating with a Research Misconduct Proceeding by carrying out the duties assigned for the purpose of helping the university meet its responsibilities pursuant to this Policy, 42 CFR Part 93, 45 CFR § 689.2, or other applicable regulation or requirement. A Committee Member does not act in Good Faith if the acts or omissions are dishonest or influenced by personal, professional,

or financial Conflict of Interest with those involved in the Research Misconduct Proceeding.[18]

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

O. *Inquiry* means preliminary information gathering and preliminary fact finding that meets the criteria provided in this Policy; in the case of PHS related support, the Inquiry follows the procedures of 42 CFR §§93.307-93.309; and, in the case of NSF related support, the Inquiry follows the procedures of 45 CFR §689.[19]

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

Q. *Inquiry Committee Report* means the written report issued by the Inquiry Committee at the end of the Inquiry Committee's proceeding.

R. *Institutional Member* means a person who is employed by, is an agent of, is a student of, or is affiliated by contract or agreement with Tulane. 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, staff members, volunteers, agents, and contractors, subcontractors, and sub awardees, and their employees.[20]

S. *Institutional Representative* means the person who assesses an Allegation of Research Misconduct to determine if it falls within the definition of Research Misconduct and warrants an Inquiry on the basis that the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified. The Institutional Representative usually is the dean of the school and/or the head of the institutional unit in which the Respondent works or studies. If more than one school or unit is involved, then the dean or director of each school and/or unit may serve as co-Institutional Representatives. The Deciding Official may serve as the Institutional Representative if circumstances warrant.

T. *Institutional Decision* means the action taken by the Deciding Official in consultation with the RIO and other appropriate university officials regarding whether to accept the

findings of an Inquiry Committee and/or an Investigation Committee, and whether to impose Administrative Action related to an Allegation of Research Misconduct.

U. *Intentionally* means acting with the intent that the action will cause a certain result.

V. *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 recommend a finding of Research Misconduct, which may include a recommendation for other appropriate action, including Administrative Action.[21]

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

X. *Investigation Committee Report* means the written report issued by the Investigation Committee at the conclusion of the Investigation Committee's proceeding.

Y. *Knowingly* means acting with awareness that the conduct will result in certain consequences.

Z. *National Science Foundation (NSF)* means the independent federal agency founded to promote the progress of science, which has issued the regulations set forth at 45 CFR Chapter VI, Parts 601 to 690, including the policies at Part 689 governing matters concerning Research Misconduct.

AA. *Notice* means a written communication served in person, sent by mail or its equivalent, or by electronic means to the last known street address, facsimile number, telephone number, or email address of the addressee.[22] When Notice is sent by email, the date of receipt is deemed to be the date the email was sent.

BB. *NSF Office of Inspector General (NSF OIG)* means the office within the NSF that oversees Investigations of alleged Research Misconduct and conducts NSF Inquiries and Investigations into Research Misconduct Allegations.

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

DD. *Research Compliance Office* means the Tulane Office of Research Compliance operating within the Tulane Office of the Vice President for Research.

EE. *Office of Research Integrity* (*ORI)* means the office to which the HHS Secretary has delegated responsibility for addressing Research integrity and Research Misconduct issues related to PHS-supported activities.[23]

FF. *Plagiarism* means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.[24] Plagiarism does not include disputes about authorship.

GG. *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.[25]

HH. *PHS Support* means PHS funding (or applications or proposals for funding) for biomedical or behavioral Research, biomedical or behavioral Research training, or activities related to that Research or training, that may be provided through funding for PHS intramural Research, PHS grants, cooperative agreements, contracts or sub grants or subcontracts under those PHS funding instruments; or salary or other payments pursuant to PHS grants, cooperative agreements or contracts.[26]

II. *Recklessly* means acting with the awareness of a substantial risk that a certain result will occur because of an action. The risk must be substantial enough that the action represents a gross deviation from what a reasonable person would do.

JJ. *Record of Research Misconduct Proceeding* means: (1) the Research Record and Evidence secured for the Research Misconduct Proceeding pursuant to this Policy, 42 CFR §§93.305, 93.307(b), 93.310(d), 45 CFR §689, and/or any other applicable regulations, except to the extent the Research Integrity Officer (RIO) 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 (other than drafts of the report) produced in the course of preparing that report, including the documentation of any decision not to investigate, as required by 42 CFR §93.309(c); and, (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.

KK. *Research* means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to generalizable knowledge (basic Research) or specific knowledge (applied Research). Research for purposes of this Policy is broadly construed and includes all basic, applied, clinical, translational and demonstration Research and artistic expression in all academic and scholarly fields and disciplines including but not limited to architecture, economics, education, engineering, humanities, linguistics, mathematics, medicine, natural sciences, public health, social sciences, social work, and Research involving human subjects and/or animals.

With regard to the PHS, 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) 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.[27] With regard to the NSF, Research includes proposals submitted to the NSF in all fields of science, engineering, mathematics and education and results from those proposals.[28]

LL. *Research Integrity Officer (RIO)* means the Tulane University Vice President for Research. The RIO is responsible for ensuring that the duties assigned to this position are carried out.

MM. *Research Misconduct* means *Fabrication*, *Falsification*, or *Plagiarism* in proposing, performing, or reviewing Research, or in reporting Research results.

1. *Fabrication* means making up data or results and recording or reporting them;
2. *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 Record;
3. *Plagiarism* means 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.[29] Plagiarism does not include disputes about authorship.

To make a finding of Research Misconduct, the Respondent's behavior must:

a) represent a significant departure from accepted practices of the relevant Research community;

b) be committed Intentionally, Knowingly, or Recklessly; and

c) be proved by a Preponderance of the Evidence.[30]

The destruction, absence of, or Respondent's failure to provide Research Records adequately documenting the questioned Research is Evidence of Research Misconduct where the university establishes by a Preponderance of the Evidence that the Respondent Intentionally, Knowingly, or Recklessly had Research Records and destroyed them; had the opportunity to maintain the records but did not do so; or maintained the 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.[31]

NN. *Research Misconduct Proceeding* means any action related to alleged Research Misconduct that is taken pursuant to this Policy.[32]

OO. *Research Record* includes but is not limited to data, documents, computer files, computer stored information, and/or written or non-written electronic or physical accounts or objects that reasonably may be expected to provide Evidence or information regarding the proposed, performed, reviewed or reported Research that constitutes the subject of an Allegation of Research Misconduct. A Research Record may include but is not limited to grant or contract applications (whether funded or unfunded); grant or contract progress and other reports; Research proposals; laboratory records (stored in physical and/or electronic form); objects; printed and electronic communications; videos; photographs; films; slides; biologic materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and/or animal subject protocols; consent forms; medical charts; patient Research files; progress reports; abstracts; theses; oral presentations; internal reports; journal articles; and any documents and materials provided by or collected from a Respondent in the course of a Research Misconduct Proceeding.[33]

PP. *Respondent* means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.[34]

QQ. *Retaliation* means an adverse action taken against a Complainant, Witness, a Committee Member and/or an Institutional Member by a person, an institution or one of its employees or affiliates in response to a Good Faith Allegation of Research Misconduct or Good Faith cooperation with a Research Misconduct Proceeding.[35]

V. Rights and Responsibilities

A. Reporting Misconduct

1. All Institutional Members have a responsibility to report observed, suspected, or apparent Research Misconduct. Institutional Members who know of or receive an Allegation of Research Misconduct must report it immediately to the RIO, an Institutional Representative, the Research Compliance Office, or through the hotline (information provided below). Schools, departments and units must not conduct a review of Allegations of Research Misconduct on their own. If an individual is unsure whether a set of circumstances falls within the definition of Research Misconduct, then the individual may contact the RIO, the Research Compliance Office or an Institutional Representative to discuss the suspected Research Misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances do not appear to meet the definition of Research Misconduct, then the RIO, an Institutional Representative or the Research Compliance Office may refer the individual or circumstances to appropriate offices or officials for handling.
2. At any time, an Institutional Member may have confidential discussions and consultations about concerns of possible Research Misconduct with an Institutional Representative, the RIO or the Research Compliance Office and will be counseled about appropriate procedures for reporting Allegations.
3. Individuals may make anonymous reports through the Tulane University Compliance Hotline by calling 1-855-546-9283 or visiting www.MyComplianceReport.com (access I.D. "TUL"). This hotline and website are operated by an independent third party who

maintains the anonymity of the person making the report while ensuring that the report is routed to proper individuals within Tulane.

B. Cooperating with Research Misconduct Proceedings

1. Institutional Members have a responsibility to cooperate fully in Research Misconduct Proceedings. Institutional Members, including the Respondent, have an obligation to provide Evidence relevant to Research Misconduct Allegations to the RIO, other university officials, Inquiry Committees and Investigation Committees.[36]
2. The Respondent to an Allegation of Research Misconduct must cooperate with the process.[37] Even if the Respondent is no longer affiliated with Tulane, Tulane must examine the Allegation and reach a conclusion. Tulane will cooperate with the Research Misconduct Proceedings of other involved institutions.

C. Maintaining Confidentiality

Disclosure of the identities of the Respondent and Complainant and the contents of records and Evidence in a Research Misconduct Proceeding is limited to the extent possible to those who need to know, consistent with a thorough, objective and fair proceeding. Exceptions include the requirement that Tulane must disclose the identities of the Respondent and Complainant to HHS in accordance with 42 CFR Part 93 and/or as required by other federal regulation or agency requirement.[38] All those involved in a Research Misconduct Proceeding have the responsibility to maintain Confidentiality to the extent reasonable and practical.[39]

D. Protecting Against Retaliation

Those who are involved in a Research Misconduct Proceeding have the right to be free of Retaliation. Institutional Members may not retaliate in any way against any other Institutional Members, Complainant, Respondent, Witnesses, or anyone involved in a Research Misconduct Proceeding. Institutional Members have a responsibility to immediately report any alleged or apparent Retaliation to the RIO. The RIO, in conjunction with university officials, will 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.[40]

E. Protecting Reputations

The RIO and other university officials will make all reasonable and practical efforts to protect or restore the reputation of a Respondent against whom no finding of Research Misconduct is made, Good Faith Complainant, Witnesses, Inquiry Committee Members, Investigation Committee Members, and Institutional Members. The method for restoring a reputation must be determined on a case-by-case basis.[41]

F. Handling Allegations Not Made in Good Faith

If circumstances warrant, the Deciding Official will determine whether a Complainant's Allegation of Research Misconduct is made without Good Faith and/or whether a Witness or Committee Member failed to act in Good Faith. If the Deciding Official determines that there was an absence of Good Faith, then the Deciding Official will determine what Administrative Action should be taken against the person who failed to act in Good Faith.

G. Rights of the Respondent

The Respondent is entitled to:

1. a Good Faith effort from the RIO to notify the Respondent in writing at the time of or before beginning the Inquiry;[42]
2. an opportunity to comment on the draft Inquiry Report and have those comments attached to the final Inquiry Report;[43]
3. be notified of the outcome of an Inquiry, and receive the final Inquiry Report, access to this Policy and any government regulations that govern the Research Misconduct Proceeding;[44]
4. if the matter proceeds to an Investigation, be notified within a reasonable time after the determination that an Investigation is warranted, but before the Investigation begins (within 30 days after the university decides to begin an Investigation); be notified in writing of any new Allegation that was not addressed in the Inquiry or in the initial Notice of Investigation within a reasonable time after the determination to pursue a new Allegation;[45]

5. be interviewed during the Investigation, have the opportunity to correct the recording or transcript of the interview, and have the corrected recording or transcript included in the record of the Investigation;[46]
6. have interviewed during the Investigation any Witness who has been identified reasonably by the Respondent as having information regarding relevant aspects of the Investigation; have the recording or transcript provided to the Witness for correction; and, have the corrected recording or transcript included in the record of Investigation;[47] and
7. receive the draft Investigation Report and, concurrently, a copy of, or supervised access to the Evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the university and addressed in the final Investigation Report.[48]

VI. Roles and Duties

A. Research Integrity Officer (RIO)

The Vice President for Research serves as the RIO and has primary responsibility for overseeing and implementing this Policy. The RIO has broad authority to administer the Policy and may delegate all or some duties throughout the process.

1. The RIO's duties include:
    a. consulting confidentially with persons who are uncertain about whether to submit an Allegation of Research Misconduct;
    b. receiving an Allegation of Research Misconduct and referring it to the appropriate Institutional Representative for an Assessment;
    c. notifying relevant government agencies, sponsors and/or university officials of Allegations of Research Misconduct as permitted by this Policy, applicable government regulations, and/or sponsor agreements.
    d. taking interim action and notifying sponsors of special circumstances in accordance with this Policy;

e. sequestering the Research Record and Evidence pertinent to an Allegation of Research Misconduct in accordance with this Policy and maintaining records securely in accordance with this Policy and applicable laws and regulations;
f. providing Confidentiality to those involved in the Research Misconduct Proceeding as required by applicable government regulations, sponsors, and/or university policies;
g. notifying the Respondent of a Research Misconduct Allegation and providing opportunities to review, comment and respond to an Allegation, Evidence, and committee reports in accordance with this Policy;
h. informing the Respondent, Complainant, and Witnesses of the procedural steps in the Research Misconduct Proceeding;
i. working with the Institutional Representative to appoint Inquiry and/or Investigation Committees whose members contain the appropriate expertise and assisting the committees in complying with this Policy and applicable government requirements;
j. working with the Institutional Representative to determine whether each person serving on an Inquiry or Investigation Committee has an unresolved personal, professional, or financial Conflict of Interest and take appropriate action, including recusal, to ensure that no person with a Conflict of Interest serves on an Inquiry or Investigation Committee;
k. taking all reasonable and practical steps to protect or restore the positions and reputations of the Respondent, Good Faith Complainant, Witnesses, Inquiry Committee Members, Investigation Committee Members, and Institutional Members while countering potential or actual Retaliation;
l. keeping the Deciding Official and others who need to know apprised of the progress of the Research Misconduct Proceeding;
m. ensuring that Administrative Action taken by the university and government agencies is enforced, including taking appropriate action to notify involved

parties, such as sponsors, law enforcement agencies, professional societies, publishers, and licensing boards; and

n. maintaining records of a Research Misconduct Proceeding in accordance with government requirements and making records available to those entities as required;
o. taking other actions necessary to perform the duties of the RIO pursuant to this Policy.

2. Notification of Allegations in Special Circumstances

At any time during a Research Misconduct Proceeding, the RIO will notify a government agency that is supporting the Research related to the Allegation when the circumstances set forth below exist. When Research involves PHS Support, the RIO immediately will notify the HHS's Office of Research Integrity. When Research involves NSF Support, the RIO immediately will notify the NSF's Office of Inspector General. Circumstances requiring notification are:

a. the health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
b. sponsor resources or interests are threatened;
c. Research activities should be suspended;
d. a reasonable indication exists of a possible violation of civil or criminal law;
e. action is required to protect the interests of those involved in the Research Misconduct Proceeding;
f. Tulane believes that the Research Misconduct Proceeding may be made public prematurely and notification will allow the sponsor to take appropriate steps to safeguard Evidence and protect the rights of those involved; or
g. the Research community or public should be informed.[49]

B. Institutional Representative

The Institutional Representative is usually the dean of the school or the director of the unit in which the Respondent is employed or studies. If more than one school or unit is involved, then the dean or director for each school or unit may serve as co-Institutional

Representatives. The Deciding Official may serve as the Institutional Representative if circumstances warrant. The Institutional Representative may delegate all or some duties throughout the process, which include:

1. receiving an Allegation of Research Misconduct; if an Allegation is received from someone other than the RIO, the Institutional Representative notifies the RIO upon receiving the Allegation;
2. providing Confidentiality to those involved in the Research Misconduct Proceeding as required by applicable government regulation, and/or university policy;
3. assessing each Allegation of Research Misconduct in accordance with this Policy to determine whether each Allegation meets the definition of Research Misconduct and warrants an Inquiry;
4. working with the RIO to appoint Inquiry and/or Investigation Committees whose members contain the appropriate expertise and assisting the committees in complying with this Policy and government requirements;
5. working with the RIO to appoint subject matter experts to assist with sequestration and the Inquiry and Investigation Committees as needed;
6. determining whether each person involved in handling an Allegation of Research Misconduct has an unresolved personal, professional, or financial Conflict of Interest and take appropriate action, including recusal, to ensure that no person with a Conflict of Interest serves on an Inquiry or Investigation Committee;
7. notifying the Respondent of the Research Misconduct Allegation and providing opportunities to review, comment and respond to the Allegation, Evidence, and committee reports in accordance with this Policy;
8. taking all reasonable and practical steps to protect or restore the positions and reputations of the Respondent, Good Faith Complainant, Witnesses, Inquiry Committee Members, Investigation Committee Members, and Institutional Members while countering potential or actual Retaliation;
9. Regarding an Inquiry Committee Report:
    a. reviewing and evaluating the Inquiry Committee Report;

b. in consultation with the RIO and other appropriate university officials, making a recommendation to the Deciding Official whether to accept the Inquiry Committee Report;

c. making a recommendation to the Deciding Official whether an Investigation is warranted. If making a recommendation that is different from the Inquiry Committee's recommendation, then state the facts that support the Institutional Representative's recommendation;

d. cooperating with the RIO in ensuring that Administrative Action taken by the university and government agencies is enforced, including taking appropriate action to notify involved parties, such as sponsors, law enforcement agencies, professional societies, publishers, and licensing boards.

10. Regarding an Investigation Committee Report:

a. reviewing and evaluating the Investigation Committee Report;

b. in consultation with the RIO and other appropriate university officials, making a recommendation to the Deciding Official whether to accept the Investigation Committee Report;

c. making a recommendation whether to accept the Investigation Committee Report. If making a recommendation different from the Investigation Committee, then state the facts that support Institutional Representative's recommendation;

d. cooperating with the RIO in ensuring that Administrative Action taken by the university and government agencies is enforced, including taking appropriate action to notify involved parties, such as sponsors, law enforcement agencies, professional societies, publishers, and licensing boards.

C. Complainant

The Complainant is responsible for making Allegations in Good Faith, maintaining Confidentiality, and cooperating with the Inquiry and/or Investigation.[50] The Complainant must be interviewed during an Investigation, if available, and must be given the transcript or recording of the interview for correction.[51]

D. Respondent

1. The Respondent has a duty to maintain Confidentiality and cooperate with the Inquiry and/or Investigation.
2. The Respondent should be given the opportunity to admit that Research Misconduct occurred and that the Respondent committed the Research Misconduct. With the advice of the RIO and university legal counsel, the Deciding Official may terminate the university's review of an Allegation that has been admitted if, for matters involving government funding, the university's acceptance of the admission and any proposed settlement is approved by the relevant government agency.[52]
3. The Respondent may choose to consult with personal legal counsel or a non-lawyer personal adviser who is not otherwise involved in the Research Misconduct Proceeding. The Respondent's personal legal counsel or personal advisor will not be allowed to participate in or attend any part of Research Misconduct Proceeding, including meetings or interviews.

E. Deciding Official

1. Regarding an Inquiry, the Deciding Official will receive the Inquiry Report and, after consulting with the RIO and other appropriate university officials as needed, decide whether an Investigation is warranted pursuant to the provisions of this Policy. A finding that an Investigation is warranted must be made in writing by the Deciding Official. In instances where PHS funding is involved, within 30 days of the finding, the funding agency must be notified and be provided with the Inquiry Report. If the Deciding Official determines that an Investigation is not warranted, then the Deciding Official and the RIO will ensure that detailed documentation of the Inquiry is retained for at least seven years after termination of the Inquiry, so that federal funding sponsors may assess the reasons why the university decided not to conduct an Investigation.[53]
2. Regarding an Investigation, the Deciding Official will receive the Investigation Report from the Investigation Committee and, after consulting with the RIO and other appropriate officials as needed, decide the extent to which the university accepts the

findings of the Investigation Report and, if Research Misconduct is found, decide what, if any, Administrative Action to take.[54] The Deciding Official will ensure that the final Investigation Report, the finding of the Deciding Official, and a description of any pending or completed Administrative Action are provided to the federal funding sponsor.

F. Interim Administrative Action; Notifying Government Agencies of Special Circumstances

1. The RIO will monitor the Research Misconduct Proceeding to determine whether any threat of harm exists to public health, federal funds and equipment, or the integrity of the Research process. If a threat is identified, the RIO will, in consultation with other university officials and applicable federal agencies, take appropriate interim Administrative Action to protect against the threat.[55] Interim Administrative Action might include additional monitoring of the Research process and the handling of federal funds and equipment; reassigning personnel or the responsibility for the handling of federal funds and equipment; and/or conducting additional review of Research data and results or delaying publication.
2. When PHS funding is involved, the RIO must, at any time during a Research Misconduct proceeding, notify ORI immediately if there is reason to believe that any of the following conditions exist:
    a. health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
    b. HHS resources or interests are threatened;
    c. Research activities should be suspended;
    d. there is a reasonable indication of possible violations of civil or criminal law;
    e. federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;
    f. Tulane believes that the Research Misconduct Proceeding may be made public prematurely and HHS action may be necessary to safeguard Evidence and protect the rights of those involved; or

g. the Research community or public should be informed.[56]

3. When the university finds, learns of, or suspects Research Misconduct that impacts or might impact the conduct or performance of NIH-supported Research, whether at the recipient organization or at a third-party sub-recipient organization, the university must work with the NIH to assess the effect on the ability to continue the project, as originally approved by the NIH. When the recipient institution finds, learns, or suspects that Falsified, Fabricated, or Plagiarized information has affected the integrity of NIH-supported Research, including but not limited to, applications for funding and progress reports, or published results of Research supported by NIH funds, the NIH has a need to know this information, and the university must immediately provide information on the affected Research to the NIH Office of Extramural Research-Research Integrity (OER-RI) in a manner consistent with the PHS Confidentiality regulations.[57]

G. Costs Associated with Research Misconduct Proceedings

Costs related to responding to Allegations of Research Misconduct and conducting Research Misconduct Proceedings will be paid by the Tulane school or unit where the Respondent works or studies. If more than one Tulane school or unit is involved, costs will be shared proportionally.

VII. Conducting the Assessment

Upon receiving an Allegation of Research Misconduct, the Institutional Representative, in coordination with the RIO, will immediately assess the Allegation to determine whether (1) the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified; and (2) the Allegation falls within the definition of Research Misconduct in this Policy.[58] An Inquiry must be conducted if these criteria are met. Allegations that do not meet these criteria will be referred to the appropriate university unit, committee or official for handling, as appropriate.

A. The Assessment period should be completed as promptly as reasonably possible. In conducting the Assessment, the Institutional Representative need not interview the Complainant, Respondent, or Witnesses, or gather data beyond any that may have been

submitted with the Allegation, except as necessary to determine whether the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.

B. The Institutional Representative may consult with subject matter experts, the RIO, the Deciding Official, and others, as needed, to complete the Assessment.

C. If the Assessment results in a finding that the Allegations do not meet the criteria for conducting an Inquiry, then the matter will be closed by the RIO and the Institutional Representative. The parties will be notified to the extent possible. If the Assessment involves Federally Sponsored Research, then the RIO must secure and maintain records and Evidence obtained during the Assessment for seven years.

VIII. Conducting the Inquiry

Upon notification from the Institutional Representative that the criteria for an Inquiry are met, the RIO will initiate the Inquiry process as described below. The purpose of the Inquiry is to conduct an initial review of the available Evidence to determine whether to conduct an Investigation. An Inquiry does not require a full review of all the Evidence related to the Allegation.[59] The Inquiry is designed to separate Allegations deserving of further Investigation from frivolous, unjustified, or clearly mistaken Allegations.

A. Notifying the Respondent

At the time of or before beginning an Inquiry, the RIO must make a reasonable, Good Faith effort to notify the Respondent in writing, if the Respondent is known, of the commencement of the Inquiry. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing.[60]

B. Sequestering Research Records

On or before the date on which the Respondent is notified or the Inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of the Research Record and Evidence needed to conduct the Research Misconduct Proceeding, inventory the records and Evidence, and sequester them in a secure manner. When the Research Record or Evidence encompasses scientific instruments shared by

multiple 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.[61] The RIO may consult with federal Research sponsors for advice and assistance in sequestering records.

C. Appointing the Inquiry Committee

The Institutional Representative, in consultation with the RIO, will appoint an Inquiry Committee within 10 days of the initiation of the Inquiry or as soon thereafter as practical. The Inquiry Committee must consist of individuals who do not have an unresolved personal, professional, or financial Conflict of Interest with those involved with the Inquiry. The Inquiry Committee will consist of individuals with the appropriate expertise to evaluate the Evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Inquiry.[62] Some or all of the members of the Inquiry Committee may be selected from outside of the university.

The RIO must make a reasonable, Good Faith attempt to notify the Respondent in writing of the names of the Inquiry Committee members. The Respondent must have 10 days from the receipt of the Notice to provide the RIO with any written objection to the Committee Members. If Notice is sent via email, the date of receipt is considered to be the date the email was sent. If no objection is received within the 10-day period, then any objection to the Inquiry Committee must be considered waived. If an objection is made, it must be made in Good Faith and must set forth in sufficient detail a reasonable basis for the objection. The Institutional Representative, in coordination with the RIO, must consider any objection. If they determine that the objection is valid, the Institutional Representative, in coordination with the RIO, must appoint one or more new members of the Inquiry Committee. If they determine that the objection is not made in Good Faith or is not valid, then the membership of the Inquiry Committee must remain the same.

D. Charging the Inquiry Committee

1. The Institutional Representative, in coordination with the RIO, will prepare a written charge for the Inquiry Committee that:
   a. identifies the Respondent;

b. sets forth the time for completing the Inquiry;
c. describes the Allegation and any related issues identified during the Assessment;
d. advises the Inquiry Committee that the purpose of the Inquiry is to conduct an initial review of the Evidence, potentially including the testimony of the Respondent, Complainant and key Witnesses, to determine whether there is sufficient substantive Evidence of possible Research Misconduct to warrant an Investigation. The purpose of the Inquiry is not to determine whether Research Misconduct definitely occurred or who was responsible;[63]
e. defines Research Misconduct;
f. 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 preliminary information-gathering and preliminary-fact finding;[64]
g. advises the Inquiry Committee that it is responsible for preparing 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);[65]
h. advises the Inquiry Committee that it must take all reasonable steps to ensure the Confidentiality of the Research Misconduct Proceeding.[66]
i. informs the Inquiry Committee that the Institutional Representative will be available throughout the Inquiry to advise the committee as needed.

E. Convening the First Meeting of the Inquiry Committee

At the Inquiry Committee's first meeting, the RIO will review the Charge with the committee, discuss the Allegation and any related issues, discuss the appropriate procedures for conducting the Inquiry, assist the committee with organizing plans for the Inquiry, and answer questions raised by the Committee. The RIO will assist the Inquiry Committee with organizing plans for the Inquiry.

F. Conducting the Inquiry

1. The Inquiry Committee has all investigative powers necessary to determine whether an Allegation of Research Misconduct should be investigated further. These powers include but are not limited to interviewing the Complainant, the Respondent and key Witnesses, and examining relevant Research Records and materials.
2. The Inquiry Committee must keep sufficiently detailed documentation of the Inquiry to permit a later analysis of the reasons for its determination.
3. The Inquiry Committee will decide whether an Investigation is warranted based on an evaluation of the Evidence obtained during the Inquiry and the criteria in this Policy. The Inquiry Committee will determine that an Investigation is warranted if:
   a. a reasonable basis exists for concluding that the Allegation falls within the definition of Research Misconduct and
   b. (i) in the case of PHS Supported funding, it involves PHS supported biomedical or behavioral Research, Research training or activities related to that Research or Research training; or

      (ii) in the case of NSF supported funding, it involves proposed or performed NSF funded research, reviewing research proposals submitted to the NSF, or reporting research results funded by the NSF for all fields of science, engineering, mathematics, and education research;[67] and
   c. preliminary information-gathering and preliminary fact-finding from the Inquiry indicate that the Allegation may have substance.[68]

      The Inquiry Committee will not decide whether Research Misconduct occurred or conduct exhaustive interviews and analyses.[69] However, if the Respondent makes a legally sufficient admission of Research Misconduct during the Inquiry, then Research Misconduct may be determined at the Inquiry stage if all relevant issues are resolved and the Respondent makes a signed, written admission that explains the Research Misconduct.[70] For Research receiving PHS Support, the RIO and Deciding Official must consult with ORI regarding the next steps to be taken in such circumstances.

G. Timing for Completing the Inquiry

The Inquiry, including preparation of the final Inquiry Report and issuance of the Deciding Official's decision whether to conduct an Investigation, must be completed within 60 calendar days of initiation of the Inquiry, unless the RIO determines that circumstances warrant a longer period. If the RIO approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 60-day period.[71] In the case of NSF sponsored Research, the Inquiry must be completed within 90 days, with the possibility of seeking an extension of time from NSF.[72]

IX. The Inquiry Report

A. Preparing the Inquiry Report

1. Once the Inquiry Committee has conducted its initial review of the Evidence and made a decision regarding whether an Investigation should be conducted, it must prepare a written Inquiry Report that includes the following information:
    a. the name and position of the Respondent;
    b. the names and titles of the Inquiry Committee Members and experts;
    c. a description of the Allegation of Research Misconduct;
    d. a description of funding for the Research involved in the Inquiry. In the case of PHS-supported Research, include grant numbers, grant applications, contracts and publications listing the PHS support;
    e. a description of the Evidence reviewed;
    f. the basis for the Inquiry Committee's recommendation regarding whether an Investigation should be conducted or should not be conducted;
    g. a recommendation regarding other steps to be taken, if any. If the Inquiry Committee determines that an Investigation is not warranted, it may recommend other actions.
    h. any comments on the draft report by the Respondent or Complainant.[73]
2. The Inquiry Committee must attach to the Inquiry Report all documents relied upon in the report.

B. Notifying the Respondent and Providing Opportunity to Comment

The RIO must notify the Respondent of the Inquiry Committee's recommendation regarding whether an Investigation is warranted or not warranted and must provide the Respondent with the draft Inquiry Report. The Respondent will be allowed 14 days to provide the RIO with comments to the draft Inquiry Report. If the draft Inquiry Report is emailed to the Respondent, the date of receipt is considered to be the date the email is sent. The Respondent must be provided with access to this Policy. For Research involving PHS Support, the Respondent must be provided with access to 42 CFR Part 93.[74] For Research involving NSF Support, the Respondent must be provided with access to 45 CFR §689.

The Respondent's comments to the draft Inquiry Report will be attached to the final Inquiry Report. Based on the comments, the Inquiry Committee may revise the report as appropriate before preparing its final Inquiry Report.[75] The committee must deliver the final Inquiry Report to the RIO.

C. Notifying the Complainant and Providing Opportunity to Comment

The RIO may notify the Complainant whether the Inquiry found that an Investigation is warranted or not warranted. The RIO may provide relevant portions of the report to the Complainant for comment.[76]

D. Making the Institutional Decision and Providing Notice

1. Institutional Decision by Deciding Official

After reviewing for compliance with this Policy, the RIO will transmit the final Inquiry Report and its attachments to the Deciding Official. The Deciding Official will determine whether an Investigation is warranted. The Deciding Official's Institutional Decision must be in writing and must state whether it: (a) accepts the Inquiry Committee's findings, including whether an Investigation is warranted; (b) accepts any other recommendations made by the Inquiry Committee; and (c) imposes any new or additional Administrative Action. In making the Institutional Decision, the Deciding Official may consult with the RIO and other appropriate university officials. The Deciding Official must give considerable weight to the findings and recommendation of

the Inquiry Committee. If the Deciding Official rejects the Inquiry Committee's findings and/or recommendations, then as part of the Institutional Decision, the Deciding Official must provide a detailed written explanation for rendering a decision different from the findings of the Inquiry Committee. Alternatively, the Deciding Official may return the report to the Inquiry committee with a request for further fact finding or analysis. The Inquiry is complete when the Deciding Official makes the Institutional Decision.

2. Notifying Government Agencies When Investigation is Warranted

   a. When PHS sponsored Research is involved, the RIO will provide ORI with the Deciding Official's written decision, the Inquiry Report, and the report's attachments. The RIO must provide the following information to ORI upon request: (1) the university's Policy used to conduct the Inquiry; (2) the Research Record and Evidence reviewed, transcripts or recordings of interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.[77]

   b. When NSF sponsored Research is involved, the RIO will immediately notify the NSF OIG when the finding of an Inquiry supports an Investigation.[78]

   c. The RIO will notify appropriate university officials of the Deciding Official's decision.[79]

3. Notifying Government Agencies When Investigation is Not Warranted

   If the Deciding Official makes an Institutional Decision not to conduct an Investigation, then the RIO must secure and maintain sufficiently detailed documentation of the Inquiry to permit a later assessment of the reasons why an Investigation was not conducted. For Research involving PHS Support, these documents must be provided to ORI or other authorized HHS personnel upon request.[80] These records must be kept for seven years after termination of the Inquiry. The university also must notify PHS, other relevant PHS agencies or any other appropriate governmental agencies of any special circumstances that may exist as explained in this Policy.[81]

E. Restoring Reputations

If an Investigation is determined to be unwarranted, the university will diligently make appropriate efforts to restore the reputation of the Respondent; protect the position and

reputation of a Complainant who made Good Faith Allegations of Research Misconduct; and protect Investigation Committee Members and Institutional Members.[82]

X. Conducting the Investigation

A. Initiating the Investigation

The Investigation must begin no later than 30 calendar days after the Institutional Decision by the Deciding Official that an Investigation is warranted.[83]

B. Purpose of the Investigation

The purpose of the Investigation is to develop a factual record by exploring the Allegation in detail and examining the Research Record and the Evidence in depth, leading to a finding that Research Misconduct has been committed or has not been committed, and if so, by whom, and to what extent. The Investigation also determines whether there are additional instances of possible Research Misconduct that would justify broadening the scope of the Investigation beyond the initial Allegation.[84]

C. Notifying Government Agencies and University Officials

1. In matters involving PHS Sponsored funding and/or NSF funding, the RIO must notify ORI (for PHS Sponsored funding) and/or the NSF OIG (for NSF Sponsored funding) of the decision to begin an Investigation on or before the date on which the Investigation begins. The notification must include the Deciding Official's Institutional Decision; the Inquiry Report with the Respondent's comments; the name of the Respondent; the application or grant number involved; this Policy; and the charge to be considered in the Investigation. Upon request, the RIO will provide the Research Records and Evidence reviewed, transcripts or recordings of interviews, and other relevant documents.[85]
2. In matters moving to Investigation, the RIO may notify appropriate university officials.

D. Sequestering Materials

On or before the date on which the Respondent is notified or the Investigation begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of the Research Record and Evidence needed to conduct the Research Misconduct proceeding that were not sequestered in the Inquiry process, inventory the records and Evidence, and sequester them in a secure manner. When the Research Record or Evidence encompasses 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.[86]

The RIO may consult with federal Research sponsors for advice and assistance in sequestering records. The need for additional sequestration of records for the Investigation may occur for multiple reasons, including the university's decision to investigate additional Allegations that were not considered during the Inquiry or the identification of records during the Inquiry that were not sequestered previously. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.[87]

E. Notifying the Respondent

At the time of or before beginning an Investigation, the RIO must make a reasonable, Good Faith effort to notify the Respondent in writing, if the Respondent is known, of the commencement of the Investigation. The RIO must also give the Respondent written Notice of any new Allegation of Research Misconduct within a reasonable amount of time after the decision is made to pursue an Allegation that was not addressed during the Inquiry or in the initial Notice of the Investigation.[88] If the Investigation subsequently identifies additional Respondents, the RIO must make a reasonable, Good Faith effort to notify them in writing.

F. Appointing the Investigation Committee

The Institutional Representative, in consultation with the RIO, will appoint an Investigation Committee within 10 days of the initiation of the Investigation or as soon thereafter as practical. The Investigation Committee must consist of individuals who do not have an

unresolved personal, professional, or financial Conflict of Interest with the Complainant, Respondent or Witnesses. The Investigation Committee will consist of individuals with the appropriate expertise to evaluate the Evidence and issues related to the Allegation, interview the principals and key Witnesses, and conduct the Investigation.[89] Members of the Inquiry Committee are eligible to serve on the Investigation Committee. Some or all of the members of the Investigation Committee may be selected from outside of the university.

The RIO must make a reasonable, Good Faith attempt to notify the Respondent in writing of the names of the Investigation Committee Members. The Respondent has 10 days from the receipt of the Notice to provide the RIO with any written objection to the Committee Members. If Notice is sent via email, the date of receipt is considered to be the date the email was sent. If no objection is received within the 10-day period, then any objection to the Investigation Committee must be considered waived. If an objection is made, it must be made in Good Faith and must set forth in sufficient detail a reasonable basis for the objection. The Institutional Representative in consultation with the RIO must consider any objection. If they determine that the objection is valid, the Institutional Representative, in coordination with the RIO, must appoint one or more new members of the Investigation Committee. If they determine that the objection is not made in Good Faith or is not valid, the membership of the Investigation Committee will remain the same.

G. Charging the Investigation Committee

The Institutional Representative, in consultation with the RIO, will define the subject matter of the Investigation in a written charge to the Investigation Committee that:

1. identifies the Respondent;
2. describes the Allegation and any related issues identified during the Inquiry;
3. defines Research Misconduct;
4. informs the committee that it 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 the Allegation;

5. advises the Investigation Committee that the purpose of the Investigation is the formal development of a factual record and the examination of that record leading to a finding of no Research Misconduct or a finding of Research Misconduct, which may include a recommendation for Administrative Action;
6. instructs the committee that it must interview the Respondent, Complainant, and any other available person who reasonably has been 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;
7. instructs the committee that it must thoroughly 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;
8. informs the committee that to determine that the Respondent committed Research Misconduct it must find that a Preponderance of the Evidence establishes that: (i) Research Misconduct, as defined in this Policy, occurred; (ii) the Research Misconduct is a significant departure from accepted practices of the relevant Research community; and (iii) the Respondent committed the Research Misconduct Intentionally, Knowingly, or Recklessly;
9. advises the 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;
10. informs the 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 Institutional Representative, will determine whether it is necessary to notify the Respondent of the new subject matter or provide Notice to additional Respondents;

11. instructs the committee to diligently pursue 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.
12. advises the Investigation Committee that it is responsible for preparing a written report of the Investigation that meets the requirements of this Policy and, in the case of Research related to PHS Support, meets the requirements of 42 CFR § 93.313 or, in the case of Research related to NSF Support, meets the requirements of 45 CFR §689.4;
13. advises the Investigation Committee that it must take all reasonable steps to ensure the Confidentiality of the Research Misconduct Proceeding;
14. sets forth the time for completing the Investigation.[90]

H. Communicating During the Investigation

During the Investigation, the Investigation Committee must keep the RIO apprised of any development that discloses (1) facts that may affect current or future funding for the Respondent; or (2) information that appropriate government agencies may need to know to ensure the appropriate use of government funds or to protect the public interest. The RIO must be responsible, in coordination with the Institutional Representative or other university officials, as appropriate, for providing Notice to the following entities regarding such developments: NSF OIG in the case of Research involving NSF Support; ORI in the case of Research involving PHS Support; and other appropriate government agencies.

I. Convening the First Meeting of the Investigation Committee

At the Investigation Committee's first meeting, the RIO will review the Charge and the Inquiry Report with the committee; discuss the Allegation and any related issues; discuss the appropriate procedures and evidentiary standards for conducting the Investigation; assist the committee with organizing plans for the Investigation; and, answer questions raised by the Committee. The Investigation Committee will be provided with access to this Policy. In the case of Research related to PHS Support, the committee will be provided with access to 42 CFR Part 93; in the case of Research related to NSF Support, the

committee will be provided with access to 45 CFR part 689. The RIO will assist the Investigation Committee with organizing plans for the Investigation. The Institutional Representative will be available throughout the Investigation to advise the committee as needed.

J. Conducting the Investigation

The Investigation Committee must:

1. 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.[91]
2. take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;[92]
3. 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 person interviewed for correction, and include the recording or transcript in the record of the Investigation;[93] and
4. pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including Evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion.[94]
5. evaluate the Evidence and testimony and determine whether, based on a Preponderance of the Evidence Standard, Research Misconduct occurred or did not occur and, if so, to what extent, and identify who committed it.
6. prepare and maintain sufficient documentation regarding its conduct of the Investigation to substantiate the Investigation Committee's findings. This documentation may be required to be provided to government agencies in accordance with applicable government requirements.

K. Completing the Investigation

1. The Investigation should be completed within 120 days of initiating the investigation, including conducting the Investigation, preparing the Investigation Report of findings, providing the draft Investigation Report to the Respondent for comment and submitting the final Investigation Report as required by this Policy.
2. If the RIO determines that the Investigation will not be completed within the 120-day period, then an extension may be granted. In the case of PHS Support, the RIO will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.[95] In the case of NSF-sponsored Research, the Investigation must be completed within 180 days with the possibility of seeking an extension of time from NSF.[96]

XI. The Investigation Report

A. Preparing the Investigation Report

The Investigation Committee is responsible for preparing a written draft report of the Investigation that includes the following information:

1. the name and position of the Respondent;
2. the names and titles of the Investigation Committee Members and experts;
3. a description of the Allegation of Research Misconduct;
4. a description of the funding for the Research involved in the Investigation. In the case of PHS-supported Research, NSF-supported Research, or other government support, include grant numbers, grant applications, contracts, and publications listing the support;
5. a description of the Evidence reviewed; the basis for the Investigation Committee's conclusions and findings; and, a decision regarding whether or not Research Misconduct was committee or was not committed and, if so, by whom and to what extent.

6. an identification and summary of the Research Record and Evidence reviewed and identify Evidence taken into custody but not reviewed; and
7. for each separate Allegation of Research Misconduct identified during the Investigation, provide a finding stating whether Research Misconduct did or did not occur. For each finding of Research Misconduct:
   a. identify whether the Research Misconduct was Falsification, Fabrication, or Plagiarism;
   b. state whether the Research Misconduct was committed Intentionally, Knowingly, or Recklessly; and
   c. identify the significant departure from accepted practices of the relevant Research community.
8. 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 the 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;
9. identify the person responsible for the Research Misconduct;
10. identify whether any publication needs correction or retraction;
11. list any current support or known applications or proposals for support that the Respondent has pending with any government agencies;
12. include comments made by the Respondent and/or the Complainant regarding the draft Investigation Report;[97]
13. a recommendation regarding other steps to be taken, if any, including Administrative Action.

B. Notifying the Complainant and Respondent and Providing Opportunity to Comment

1. The Respondent
   a. The RIO must give the Respondent the draft Investigation Report for comment and, concurrently, a copy of or supervised access to the Evidence on which the report is based. In distributing the draft Investigation Report to the Respondent, the RIO will inform the Respondent of the Confidentiality of the report and may

establish reasonable conditions to ensure Confidentiality such as signing a Confidentiality agreement.

b. The Respondent will be allowed 30 days from the date the Respondent receives the draft report to submit comments to the RIO. If the draft Investigation Report is emailed to the Respondent, the date of receipt is considered to be the date the email is sent. For Research involving PHS Support, the Respondent must be provided with access to 42 CFR Part 93. For Research involving NSF Support, the Respondent must be provided with access to 45 CFR §689. The Respondent must be provided with this Policy.[98] The Respondent's comments to the draft Investigation Report will be attached to the final Investigation Report. Based on the comments, the Investigation Committee may revise the report as appropriate before preparing its final Investigation Report. The committee must deliver the final Investigation Report to the RIO.[99]

2. Complainant

The RIO may provide the Complainant the draft Investigation Report or relevant portions of the report. If the RIO provides the Complainant with the draft Investigation Report, then the Complainant will be allowed 30 days from the date the Complainant received the draft Investigation report or relevant portions of it to submit comments to the RIO. If the draft Investigation Report is emailed to the Complainant, the date of receipt is considered to be the date the email is sent. If the Complainant comments on the draft report, the comments must be included and considered in the final report.

C. Making the Institutional Decision and Providing Notice

1. Institutional Decision by the Deciding Official

After reviewing for compliance with this Policy, the RIO will transmit the final Investigation Report and its attachments to the Deciding Official. The Deciding Official will make the written Institutional Decision regarding (1) whether the university accepts the Investigation Report, its findings, and any recommended Administrative Action; and (2) whether to impose any new or additional Administrative Action. In

making the Institutional Decision, the Deciding Official may consult with the RIO and other appropriate university officials. The Deciding Official must give considerable weight to the findings and recommendation of the Investigation Committee. If the Deciding Official rejects the Investigation Committee's findings and/or recommendations, then as part of the Institutional Decision, the Deciding Official must provide a detailed written explanation for rendering a decision different from the findings of the Investigation Committee. Alternatively, the Deciding Official may return the report to the Investigation Committee with a request for further fact-finding or analysis. The Institutional Decision must document Administrative Action imposed on the Respondent. The Investigation is completed when the Deciding Official completes the Institutional Decision.

2. Notifying the Respondent

   The Deciding Official must notify the Respondent in writing of the Investigation Committee's findings and the Institutional Decision. The Deciding Official must provide the Respondent with the Institutional Decision and the final Investigation Committee Report and must provide a copy to the RIO.

3. Notifying Government Agencies

   Unless an extension has been granted, by the end of the 120-day period for completing the Investigation, the RIO will submit the following to ORI in matters involving PHS Sponsored Research. In matters involving NSF Sponsored Research, the RIO will submit the following information to NSF OIG within the 180-day period for completing the report:

   a. the final Investigation Report with all attachments;
   b. a statement of whether the university accepts the findings of the Investigation 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 Action.[100]

D. Notifying Others

Working in cooperation, the Deciding Official and the RIO may notify appropriate university officials. The Deciding Official, the RIO and appropriate university officials will cooperate to determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals, collaborators of the Respondent regarding the subject matter of the Investigation, or other relevant entities or individuals should be notified of the outcome of the proceeding and how the notification should be made. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The Deciding Official is responsible for signing the required notifications.

E. Maintaining Records

The RIO must maintain the records of the Research Misconduct Proceeding in a secure manner for the time period specified below after the date on which the Investigation concludes or any PHS, NSF or other federal government 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 or unless custody has been transferred to HHS as provided for by 42 CFR § 93.317(5)(c).[101] The RIO is responsible for providing any information, documentation, Research Records, Evidence or clarification requested by ORI to carry out its review of an Allegation of Research Misconduct or of the university's handling of the Allegation.[102]

a. For Federally-Sponsored Research, the RIO must keep all records from the Inquiry Committee or otherwise related to the Inquiry in a secure manner for seven years after the later of the date on which the Inquiry or any subsequent Investigation concluded, unless ORI has advised the RIO in writing that the university no longer needs to retain the records. All records must be made available upon request to government agencies as required by applicable government regulations.[103]

b. For Research that is not Federally-Sponsored Research, the RIO must keep all records from the Inquiry Committee, Investigation Committee or otherwise related to the

Inquiry and/or Investigation in a secure manner for three years after the later of the date on which the Inquiry or any subsequent Investigation concluded.

XII. Completing Inquiries and Investigations; Reporting Premature Closures

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. In the case of PHS Sponsored Research, the RIO must notify ORI in advance if the university plans to close a matter at the Inquiry stage or before an Investigation is completed. Early termination is permitted when the Respondent admits committing Research Misconduct and a settlement with the Respondent has been reached.

If a completed Investigation results in a finding of no Research Misconduct, this finding must be reported to ORI for PHS-sponsored Research as required in this Policy and 42 CFR § 93.315 or to OIG for NSF-sponsored Research, as required in this Policy and 45 CFR §689.4.[104] The resignation or termination of the Respondent before the conclusion of an Inquiry or Investigation is not sufficient justification to terminate an Inquiry or Investigation early.

XIII. Institutional Administrative Action

If the Deciding Official determines that Research Misconduct is substantiated by the findings of an Investigation, the Deciding Official will determine the Administrative Action to be taken, after consulting with the RIO and other appropriate university officials. The Administrative Action may include:

A. withdrawal or correction of all pending or published abstracts and papers emanating from the Research where Research Misconduct was found;
B. 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;
C. restitution of funds to the grantor agency as appropriate; and other action appropriate to the Research Misconduct.

XIV. Other Considerations for Inquiries and Investigations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's university employment, by resignation or otherwise, before or after an Allegation of Research Misconduct has been reported, must not be sufficient justification to preclude or terminate the Research Misconduct proceeding or otherwise limit any of the university's responsibilities under 42 CFR Part 93 or 45 CFR Part 698.

If the Respondent, without admitting to the Research Misconduct, elects to resign after the university receives an Allegation of Research Misconduct, then 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 Research Misconduct Process after resignation, then the RIO and any Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning the Allegation, noting in the report the Respondent's failure to cooperate and its effect on the Research Misconduct Proceeding.

B. Restoration of Reputations

Following an Institutional Decision of no Research Misconduct, including ORI concurrence where required by 42 CFR Part 93 or NSF concurrence where required by 45 CFR Part 689, the RIO will, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation.[105] Depending on the particular circumstances and the views of the Respondent, the RIO should consider notifying those individuals who are aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the Allegation of Research Misconduct was previously publicized, and expunging all reference to the Research Misconduct Allegation from the Respondent's personnel file. Any Administrative Action to restore the Respondent's reputation should first be approved by the Deciding Official in coordination with the RIO and appropriate university officials.

ENDNOTES

[1] 42 CFR §§93.100, 93.300
[2] 42 CFR §93.102
[3] 42 CFR §93.105(b)(1)
[4] 42 CFR §93.105(b)(2)
[5] 42 CFR §93.300
[6] 42 CFR §93.200
[7] 42 CFR §93.201
[8] 42 CFR §93.203
[9] 42 CFR §93.108(a)
[10] 42 CFR §93.108
[11] 42 CFR §93.208
[12] 42 CFR §93.219
[13] 42 CFR §93.106(b)
[14] 42 CFR §93.106(b)(2)
[15] 42 CFR §§93.106, 93.219
[16] 42 CFR §93.103(a)
[17] 42 CFR §93.103(b)
[18] 42 CFR §93.210
[19] 42 CFR §93.212
[20] 42 CFR §93.214
[21] 42 CFR §93.215; 45 CFR §689.2(b)
[22] 42 CFR §93.216
[23] 42 CFR §93.217
[24] 42 CFR §93.103(c)
[25] 42 CFR §93.219
[26] 42 CFR §93.221
[27] 42 CFR §93.222
[28] 45 CFR §689.1(a)(4)
[29] 42 CFR §93.103; 45 CFR §689.1
[30] 42 CFR §93.104; 45 CFR § 689.2(c)
[31] 42 CFR §93.106
[32] 42 CFR §93.223
[33] 42 CFR §93.224
[34] 42 CFR §93.225
[35] 42 CFR §93.226
[36] 42 CFR §93.300
[37] 42 CFR §93.300
[38] 42 CFR §93.108
[39] 42 CFR §93.108
[40] 42 CFR §93.300(d)
[41] 42 CFR §§93.304(k) and (l)
[42] 42 CFR §§93.304(c), 93.307(b)
[43] 42 CFR §§93.304(e), 93.307(f)
[44] 42 CFR §308(a)
[45] 42 CFR §310(c)
[46] 42 CFR §310(g)
[47] 42 CFR §310 (g)
[48] 42 CFR §§93.304(f), 93.312(a)
[49] 42 CFR §93.318; 45 CFR §689.4(c)

[50] 42 CFR §93.203, 93.210
[51] 42 CFR §93.310(g)
[52] 42 CFR §93.316
[53] 42 CFR §93.309(c)
[54] 42 CFR §93.304(h)
[55] 42 CFR §93.304(h)
[56] 42 CFR §93.318
[57] 42 CFR §93.108; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html
[58] 42 CFR §93.307(a)
[59] 42 CFR §93.307(c)
[60] 42 CFR §93.307(b)
[61] 42 CFR §§93.305(a), 93.307(b)
[62] 42 CFR §93.304(b)
[63] 42 CFR §93.307(c)
[64] 42 CFR §93.307(d)
[65] 42 CFR §93.307(e)
[66] 42 CFR §93.108
[67] 45 CFR §689.1
[68] 42 CFR §93.307(d)
[69] 42 CFR §93.307(c)
[70] 42 CFR §93.316(a)
[71] 42 CFR §93.307(g)
[72] 45 CFR §689.4(b)(1)
[73] 42 CFR §93.309(a)
[74] 42 CFR §93.308(a)
[75] 42 CFR §93.307(f)
[76] 42 CFR §93.308
[77] 42 CFR §93.309
[78] 45 CFR §689.4(b)(2)
[79] 42 CFR §§93.309(a) and (b)
[80] 42 CFR §93.309(c)
[81] 42 CFR §93.309(d)
[82] 42 CFR §93.300(d)
[83] 42 CFR §93.310(a)
[84] 42 CFR §§93.215, 93.104, 93.310(c)
[85] 42 CFR §§93.309(a), 310(b)
[86] 42 CFR §§93.305, 93.307(b), 93.310(b)
[87] 42 CFR §93.310(d)
[88] 42 CFR §93.310(b) and (c)
[89] 42 CFR §93.304(b)
[90] 42 CFR §§93:104, 93:106(a), 93:106(b)(2); 93:300(e), 93:304(a), 93:309, 93:310, 93:311
[91] 42 CFR §93.310(e)
[92] 42 CFR §93.310(f)
[93] 42 CFR §93.310(g)
[94] 42 CFR §93.310 (h)
[95] 42 CFR §93.311
[96] 45 CFR §689.4(b)(4)
[97] 42 CFR §93.313(f)
[98] 42 CFR §93.312(a)
[99] 42 CFR §§93.312(a), 313(g)
[100] 42 CFR §93.315
[101] 42 CFR §93.317 (b)
[102] 42 CFR §§93.300(g), 93.403(b) and (d)

[103] 42 CFR §93.317(b)
[104] 42 CFR §93.316(a)
[105] 42 CFR §93.304(k)