Tulane University Policies and Procedures for Addressing Allegations of Research Misconduct

RESPONSIBLE UNIVERSITY OFFICIAL: Research Integrity Officer (RIO)

RESPONSIBLE OFFICE: Vice President for Research

COORDINATING DEPARTMENTS: Office of Research Compliance and Research Integrity (RCO)

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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 effectively and expeditiously address 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

^{1 42} CFR §93.100, §300

² 42 CFR §93.102

- 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:
 - the respondent continues or renews an incident of alleged research misconduct that
 occurred before the six-year time limitation and does so through the use of,
 republication of or citation to the portion(s) of the research record (e.g., processed
 data, journal articles, funding proposals, data repositories) alleged to have been
 fabricated, falsified, or plagiarized, for potential benefit of the respondent.
 - a. When the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by the U.S. Department of Health and Human Services (HHS) or the university, this exception applies.
 - b. For research misconduct that appears subject to the subsequent use exception, a determination that the subsequent use exception does not apply must be documented. For PHS-supported activities, such documentation must be retained in accordance with 42 CFR §93.318.3

^{3 42} CFR §93.104

- 2. If 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, this exception applies.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:
 - 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;
 - 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;
 - takes all reasonable and practical steps to protect the research process during a research misconduct proceeding;
 - takes all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation (see Protecting Against Retaliation, below);

^{4 42} CFR §93.104(b)(2)

- 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 reasonable and 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 other 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.

A. Accepted practices of the relevant research community means, for PHS-supported activities, those practices established by 42 CFR part 93 and by PHS funding components.

Accepted practices also mean commonly accepted professional codes or norms within the

^{5 42} CFR §93.300

- overarching community of researchers and institutions that apply for and receive PHS and other sponsored research awards.⁶
- B. 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 the health and safety of the public; to promote the integrity of research and/or research training (including but not limited to biomedical or behavioral research); or activities related to that research or research training; to conserve public funds; ⁷ to protect the university's 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.
- C. Allegation means a disclosure of possible research misconduct through any means of communication and brought directly to the attention of a university official.⁸
- D. Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; for PHS jurisdiction, appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.⁹
- E. Committee Member means a member of a committee that Tulane appoints for the purpose of conducting a research misconduct proceeding regarding an allegation of research misconduct pursuant to this policy.
- F. Complainant means an individual who in good faith makes an allegation of research misconduct. ¹⁰ A complainant may make an allegation anonymously and request that anonymity be preserved throughout the proceeding.

^{6 42} CFR §93.200

⁷ 42 CFR §93.201

^{8 42} CFR §93.203

⁹ 42 CFR §93.204

^{10 42} CFR §93.206

- G. Confidentiality means that the disclosure of the identity of a respondent, complainant, and witnesses while conducting the research misconduct proceeding is limited, to the extent possible, to those who need to know, as determined by the university, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure of the identify of respondents, complainants, and witnesses no longer applies once the university has made a final determination of research misconduct findings. The university is not prohibited from managing published data or acknowledging that data may be unreliable. For PHS-supported activities, the university must disclose the identity of a respondent, complainant, or other relevant persons to the HHS's Office of Research Integrity (ORI) pursuant to its review the research misconduct proceeding. Except as otherwise prescribed by applicable law, confidentiality must be maintained for records or evidence from which research subjects might be identified. 11
- H. *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.
- Day means calendar day unless otherwise specified. If a deadline falls on a Saturday,
 Sunday or federal holiday, then the deadline will be extended to the next day this is not a
 Saturday, Sunday or federal holiday.¹²
- J. *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.
- K. Evidence means anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.¹³

¹¹ 42 CFR §93.106

^{12 42} CFR §93.208

^{13 42} CFR §93.210

- L. *Evidentiary standards* mean 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 evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not. ¹⁴ 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 making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the university establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request. ¹⁵
 - ii. The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. In determining whether the university has carried the burden of proof, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.¹⁶
 - iii. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.¹⁷

¹⁴ 42 CFR §93.105(a), §228

^{15 42} CFR §93.105(b)(1)

¹⁶ 42 CFR §93.105(b)(2)

¹⁷ 42 CFR §93.105(b)(3)

- M. Fabrication means making up data or results and recording or reporting them. 18
- N. *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.¹⁹
- O. 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.
- P. Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity covered by PHS regulations 42 CFR Part 93 involving research or research training; funding components may be agencies, bureaus, centers, institutes, divisions, offices, or other awarding units within the PHS.²⁰
- Q. Good faith means having a reasonable belief in the truth of one's allegation or testimony based on the information known to the individual (such as a complainant or witness) 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 knowledge of or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to an institutional or committee member means cooperating with a research misconduct proceeding by impartially 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. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceeding are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.²¹
- R. Health and Human Services means the United States Department of Health and Human Services.

¹⁸ 42 CFR §93.211

¹⁹ 42 CFR §93.212

²⁰ 42 CFR §93.213

^{21 42} CFR §93.214

- S. *Inquiry* means preliminary information gathering and preliminary fact finding that meets the criteria provided in this policy; in the case of PHS-supported activities, the inquiry follows the procedures of 42 CFR §93.307 through §93.309; and, in the case of NSF related support, the inquiry follows the procedures of 45 CFR §689.²²
- T. Inquiry report means the written report issued at the conclusion of the inquiry that meets the requirements of the inquiry as described in this policy.²³
- U. *Institutional certifying official* means the institutional official responsible for assuring on behalf of the university that the university has written policies and procedures for addressing allegations of research misconduct and complies with its own policies and procedures. The institutional certifying official is responsible for certifying the content of the institution's annual PHS report, which contains information specified by ORI on the institution's compliance with 42 CFR Part 93 and ensuring the report is submitted to ORI as required.²⁴
- V. *Institutional deciding official* means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the institutional deciding official and the RIO.²⁵
- W. *Institutional member* means an individual 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, technicians, postdoctoral and other fellows, students, staff members, volunteers, subject matter experts, consultants, or attorneys or employees or agents of contractors, subcontractors, or sub-awardees.²⁶

X. *Institutional record* means:

 the records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to:

²² 42 CFR §93.215

²³ 42 CFR §93.307(g)

^{24 42} CFR §93.217

²⁵ 42 CFR §93.218

^{26 42} CFR §93.219

- a. documentation of the assessment as required by 42 CFR §93.306(c) in instances where PHS-supported activities are involved.
- b. If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by 42 CFR §93.309(c) in instances where PHS-supported activities are involved.
- c. If an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to 42 CFR §93.310(g), and information the respondent provided to the institution in instances where PHS-supported activities are involved.
- d. Decision(s) by the institutional deciding official, such as the written decision from the deciding official pursuant to 42 CFR §93.314 in instances where PHS-supported activities are involved.
- e. In instances involving PHS-supported activities, a single index listing all the research records and evidence that the university compiled during the research misconduct proceeding, except records the university did not consider or rely on.
- f. In instances involving PHS-supported activities, a general description of the records that were sequestered but not considered or relied on.²⁷
- Y. 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

²⁷ 42 CFR §93.220

- representatives. The deciding official may serve as the institutional representative if circumstances warrant.
- Z. 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 and/or investigation, and whether to impose administrative action related to an allegation of research misconduct.
- AA. Intentionally means acting with the aim of carrying out the act.²⁸
- BB. *Investigation* means the formal development of a factual record and the examination of that record. In instances involving PHS-supported activities, investigation also includes the criteria and procedures of 42 CFR §93.310 through §93.317.²⁹
- CC. *Investigation committee* means the group of individuals appointed to conduct an investigation pursuant to this policy.
- DD. *Investigation committee report* means the written report issued by the investigation committee at the conclusion of the investigation.
- EE. Knowingly means acting with awareness of the act. 30
- FF. 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.
- GG. *Notice* means a written or electronic communication served in person, or sent by mail or its equivalent to the last known street address, facsimile number, or email address of the addressee. ³¹ When notice is sent by email, the date of receipt is deemed to be the date the email was sent.
- HH. *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.

²⁸ 42 CFR §93.221

²⁹ 42 CFR §93.222; 45 CFR §689.2(b)

^{30 42} CFR §93.223

^{31 42} CFR §93.224

- II. *NSF support* means NSF funding (or applications or proposals for funding) for any type of research, related training, or education.
- JJ. Office of Research Integrity (ORI) means the office established by Public Health Service Act section 493 (42 U.S.C. §289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.³²
- KK. *Person* means any individual, corporation, partnership, institution, association, unit of government, or other legal entity, however organized.³³
- LL. *Plagiarism* means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
 - Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology.
 - Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.³⁴
- MM. Preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.³⁵
- NN. *Public Health Service* (PHS) consists of the following components within HHS: the Office of the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and

^{32 42} CFR §93.225

^{33 42} CFR §93.226

^{34 42} CFR §93.227

^{35 42} CFR §93.228

Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and any other components of HHS designated or established as components of the Public Health Service.³⁶

- OO. *PHS support* or PHS-supported activities means PHS funding (or applications or proposals for PHS 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, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments pursuant to PHS grants, cooperative agreements or contracts.³⁷
- PP. *Recklessly* means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification or plagiarism.³⁸
- QQ. *Research* means a systematic study (whether funded or unfunded) directed toward fuller knowledge or understanding of the subject studied and that is conducted at, under the auspices of, and/or using the resources of, the university.

With regard to PHS-supported activities, 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) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions or effects; diseases; treatments; or related matters to be studied.³⁹ 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.⁴⁰

^{36 42} CFR §93.229

³⁷ 42 CFR §93.230

^{38 42} CFR §93.231

^{39 42} CFR §93.232

^{40 45} CFR §689.1(a)(4)

- RR. Office of Research Compliance and Research Integrity (Office of Research Compliance or RCO) means the Tulane office of this name operating within the Tulane Office of the Vice President for Research.
- SS. Research Integrity Officer (RIO) means the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93; 45 CFR Chapter VI, Parts 601 to 690; and all other applicable regulations. ⁴¹ At Tulane, the RIO is the Tulane Vice President for Research or another university official designated by the Provost. The RIO is responsible for ensuring that the duties assigned to this role are carried out.
- TT. Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - Research misconduct does not include honest error or differences of opinion.⁴²
 Plagiarism does not include disputes about authorship.
 - 2. 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.⁴³
- UU. Research misconduct proceeding means any actions related to alleged research misconduct that is taken pursuant to this policy including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals pursuant to 42 CFR Part 93.⁴⁴
- VV. Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include but are not limited to research proposals (whether funded or unfunded), raw

⁴¹ 42 CFR §92.233

⁴² 42 CFR §93.234; 45 CFR §689.1

^{43 42} CFR §93.103; 45 CFR § 689.2(c)

^{44 42} CFR §93.235

data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts and other publications, abstracts, theses, records of oral presentations, online content, laboratory meeting reports, journal articles, ⁴⁵ videos, photographs, films, slides, biologic materials, computer files and printouts, equipment use logs, laboratory procurement records, animal facility records, human and/or animal subject protocols, consent forms, medical charts, patient research files, and/or internal reports.

- WW. *Respondent* means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.⁴⁶
- XX. 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 members or affiliates in response to:
 - 1. a good faith allegation of research misconduct
 - 2. or good faith cooperation with a research misconduct proceeding.⁴⁷

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

^{45 42} CFR §93.236

⁴⁶ 42 CFR §93.237

⁴⁷ 42 CFR §93.238

- 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.
- 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 <u>Research Compliance Office</u> 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

- Institutional members have a responsibility to cooperate fully in research misconduct proceedings. Institutional members and the respondent have an obligation to provide evidence relevant to research misconduct allegations to the RIO, other university officials, and committees and/or persons involved in research misconduct proceedings such as investigation committees.⁴⁸
- The respondent must cooperate with the process.⁴⁹ 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

All those involved in a research misconduct proceeding have the responsibility to maintain confidentiality to the extent reasonable and practical. Disclosure of the identities of the respondent, complainant, and witnesses while conducting the research misconduct proceedings and the contents of records and evidence in a research misconduct

⁴⁸ 42 CFR §93.214, §300(f)

^{49 42} CFR §93.300(f)

proceeding is limited, to the extent possible, to those who need to know as determined by the university, consistent with a thorough, objective, and fair proceeding and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once the institution has made a final determination of research misconduct findings.

Exceptions include the requirement that Tulane must disclose the identities of respondents, complainants, or other relevant persons to ORI in accordance with 42 CFR Part 93 when PHS-supported activities are involved and/or as required by other federal regulation or agency requirement. These confidentiality provisions do not prohibit Tulane from managing published data or acknowledging that data may be unreliable. Tulane from managing published data or acknowledging that data may be unreliable.

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 member, complainant, respondent, witnesses, or anyone who participates in good faith 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.⁵²

E. Protecting Reputations

The RIO and other university officials will make all reasonable and practical efforts to protect or restore the reputation of respondents against whom no finding of research misconduct is made, good faith complainants, witnesses, committee members involved in the research misconduct process, and institutional members. The method for restoring a reputation must be determined on a case-by-case basis.

⁵¹ 42 CFR §93.106(d)

⁵⁰ 42 CFR §93.106

^{52 42} CFR §93.300(d)

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;⁵³
- 2. an opportunity to comment on the draft inquiry report and have those comments attached to the final inquiry report;⁵⁴
- 3. be notified of the outcome of an inquiry; receive the final inquiry report; and be provided with access to or refer to this policy and any government regulations that govern the research misconduct proceeding;⁵⁵
- 4. if the matter proceeds to an investigation, be notified in writing 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(s) 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(s);⁵⁶
- 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;⁵⁷

^{53 42} CFR §93.307(c)

⁵⁴ 42 CFR §93.307(g)(3)

^{55 42} CFR §308(a)

⁵⁶ 42 CFR §310(c)

^{57 42} CFR §310(g)

- 6. have interviewed during the investigation any witness who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent; have the recording or transcript provided to the witness for correction; and, have the corrected recording or transcript included in the record of investigation;⁵⁸ and
- 7. receive the draft investigation report and, concurrently, a copy of, or supervised access to the research records and other evidence that the investigation committee considered or relied on. The respondent's comments, if any, must be submitted to the RIO within 30 days of receiving the draft investigation report.⁵⁹

VI. Roles and Duties

A. Research Integrity Officer (RIO)

The Vice President for Research or another university official designated by the Provost 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;
- 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;

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^{58 42} CFR §310(g)

⁵⁹ 42 CFR §93.310(g), §312(a)

- e. sequestering the research record and other 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;
- working with the institutional representative to appoint a research misconduct committee whose members contain the appropriate expertise and assisting the committee in complying with this policy and applicable government requirements;
- j. working with the institutional representative to determine whether each person serving on a research misconduct 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 a committee;
- taking all reasonable and practical steps to protect or restore the positions and reputations of the respondent, good faith complainant, witnesses, committee members, and institutional members while countering potential or actual retaliation;
- 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
- 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.

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:

- 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;
- 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 an individual or a committee for an inquiry and/or members of an investigation committees and/or subject matter experts who have the appropriate expertise to assist in complying with this policy and government requirements;
- 5. 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 a research misconduct committee or as a subject matter expert for a research misconduct proceeding;
- notifying the respondent of the research misconduct allegation and providing opportunities to review, comment and respond to the allegation, evidence, and reports in accordance with this policy;
- 7. taking all reasonable and practical steps to protect or restore the positions and reputations of the respondent, good faith complainant, witnesses, committee members, and institutional members while countering potential or actual retaliation;
- 8. regarding an inquiry report:
 - a. reviewing and evaluating the inquiry report;
 - in consultation with the RIO and other appropriate university officials, making a
 recommendation to the deciding official whether to accept the inquiry report;
 If making a recommendation that is different from the inquiry recommendation,
 then state the detailed facts and rationale that support the institutional
 representative's recommendation;
 - c. 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.
- 9. Regarding an investigation committee report:
 - a. reviewing and evaluating the investigation committee report; in consultation with the RIO and other appropriate university officials, making a recommendation to the deciding official whether to accept the investigation committee report. If making a recommendation different from the investigation committee, then the institutional representative must state the detailed facts and rationale that support institutional representative's recommendation;
 - b. 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.⁶⁰ The complainant must be interviewed during an investigation, if available, and must be given the transcript or recording of the interview for correction.⁶¹

D. Respondent

- 1. The respondent has a duty to maintain confidentiality and cooperate with the research misconduct proceeding 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, and in matters involving PHS support, complies with 42 CFR §93.317.62
- 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 the research misconduct proceeding, including meetings or interviews.⁶³

E. Deciding Official

 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

^{60 42} CFR §93.206, §214

^{61 42} CFR §93.310(g)

^{62 42} CFR §93.317

whether an investigation is warranted pursuant to the provisions of this policy. The decision of whether or not an investigation is warranted must be made in writing by the deciding official. In instances where PHS-supported activities are involved, within 30 days of the finding, ORI 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.⁶⁴

- 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, make a final determination of research misconduct findings. This determination must be provided in a written decision that includes:
 - a. whether the university found research misconduct and, if so, who committed the misconduct and
 - b. a description of relevant university actions taken or to be taken. 65
- The deciding official will ensure that the final investigation report, the finding of the deciding official, and a description of any planned or completed administrative action are provided to the sponsor as may be required and, in matters involving PHS support, to ORI.⁶⁶
- 4. The deciding official may delegate all or some duties throughout the process.
- F. Interim Administrative Action; Notifying Government Agencies of Special Circumstances
 - 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

^{64 42} CFR §93.309(a), §309(c), §318

^{65 42} CFR § 93.314

^{66 42} CFR §93.316

- administrative action to protect against the threat. 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.⁶⁷
- 2. 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 university 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.⁶⁸

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. General Conduct of Research Misconduct Proceedings

A. Sequestration of research records and other evidence.

Tulane will promptly take all reasonable and practical steps to obtain all research records and other evidence, which may include copies of the data or other evidence, so long as those copies are substantially equivalent in evidentiary value, needed to conduct the

^{67 42} CFR §93.305(g)

^{68 42} CFR §93.305(g); https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html

research misconduct proceeding; inventory the research records and/or other evidence and sequester them in a secure manner. Where the research records or other evidence are located on or encompass scientific instruments shared by multiple users, Tulane may obtain copies of the data or other evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments. Whenever possible, Tulane must obtain the research records or other evidence:

- 1. before or at the time the respondent is notified of the allegation(s) and
- 2. whenever additional items become known or relevant to the inquiry or investigation.
- B. Where appropriate, Tulane must give the respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with the provisions above.
- C. Maintenance of sequestered research records and other evidence. Tulane must maintain the sequestered research records and other evidence as required by part 42 CFR §93.318 related to PHS-supported activities.
- D. If the university identifies additional respondents during an inquiry or investigation, it is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided notice of and an opportunity to respond to the allegations, consistent with this policy.
- E. When allegations involve research conducted at multiple institutions, one institution must be designated as the lead institution if a joint research misconduct proceeding is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.
- F. Using a committee, consortium, or other person for research misconduct proceedings.

- Tulane must address any potential, perceived or actual personal, professional or financial conflicts of interest between members of the committee or consortium, or other person, and the complainant, respondent or witnesses.
- Tulane must ensure that a committee, consortium, or person acting on its behalf conducts research misconduct proceedings in compliance with the requirements of 42 CFR Part 93 when PHS-supported activities are involved.⁶⁹

G. Notification of Special Circumstances

At any time during a research misconduct proceeding, Tulane must notify the 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 ORI. 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. appropriate steps may need to be taken to safeguard evidence and protect the rights of those involved.⁷⁰

VIII. Conducting the Assessment

- A. An assessment's purpose is to determine whether an allegation warrants an inquiry.
- B. Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:

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^{69 42} CFR §93.305

^{70 42} CFR §93.305(g); 45 CFR §689.4(c)

- 1. falls within the definition of research misconduct;
- 2. is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

For matters involving PHS-supported activities, the assessment also must include a determination whether the criteria of 42 CFR §93.102 apply.

- C. An inquiry must be conducted if the allegation meets the three assessment criteria in paragraph B of this section. Allegations that do not meet these criteria will be referred to the appropriate university unit, committee or official for handling, as appropriate.
- D. If the RIO or another designated university official determines that requirements for an inquiry are met, they must:
 - a. document the assessment; and
 - promptly sequester all research records and other evidence and promptly initiate the inquiry. For matters involving PHS-supported activities, the sequestration must be consistent with 42 CFR §93.305(a).
- E. If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI (when PHS support is involved) of the reasons why the institution did not conduct an inquiry. Such documentation must be retained in accordance with 42 CFR §93.318 when PHS support is involved.⁷¹
- F. The Institutional representative may consult with subject matter experts, the RIO, the deciding official, and others, as needed, to complete the assessment.

IX. Conducting the Inquiry

- A. An inquiry is warranted if the allegation meets the following three criteria:
 - 1. falls within the definition of research misconduct in this policy;
 - is within the applicability criteria of 42 CFR §93.102 for PHS-supported activities;

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^{71 42} CFR §93.306

- 3. is sufficiently credible and specific so that potential evidence of research misconduct may be identified.⁷²
- B. An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of the evidence related to the allegation.⁷³
- C. At the time of or before beginning an inquiry, a good faith effort must be made to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the university must notify them. Only allegations specific to a particular respondent are to be included in the notification to that respondent. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.⁷⁴
- D. The university must obtain all research records and other evidence needed to conduct the research misconduct proceeding. When PHS-supported activities are involved, the sequestration must be consistent with 42 CFR §93.305(e).⁷⁵
- E. Conducting the inquiry
 - When multiple institutions are involved, a joint research misconduct proceeding must be conducted consistent with 42 CFR 93.305(e) when PHS-supported activities are involved.
 - 2. The university may convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted. The inquiry review may be done by the RIO or other designated institutional official in lieu of a committee, with the caveat that if needed, these individuals may utilize one or more subject matter experts to assist them in the inquiry. If an inquiry committee is appointed, the committee generally should consist of three members unless circumstances necessitate otherwise.

⁷² 42 CFR §93.307(a)

⁷³ 42 CFR §93.307(b)

⁷⁴ 42 CFR §93.307(c)

⁷⁵ 42 CFR §93.307(d)

- 3. The university may interview witnesses or respondents that would provide additional information for the university's review.⁷⁶
- 4. An investigation is warranted if:
 - a. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this policy and, in the case of PHSsupported activities, involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in 42 CFR §93.102; and
 - b. preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.
- 5. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing or reckless, cannot be made at the inquiry stage.⁷⁷

F. Inquiry report

The university must prepare a written report as described below in the section entitled Preparing the Inquiry Report. When PHS support is involved, the report must meet the requirements of this section and 42 CFR §93.309. If there is potential evidence of honest error or difference of opinion, the university must note this in the inquiry report. The university must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report as explained below in the section below entitled Notifying the Respondent and Providing Opportunity to Comment. ⁷⁸

G. Time for completion

1. The inquiry must be completed within 90 days of its initiation unless circumstances warrant a longer period.

⁷⁶ 42 CFR §93.307(e)

⁷⁷ 42 CFR §93.307(f)

^{78 42} CFR §93.307(g)

- 2. In the case of PHS-supported activities, if the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period.⁷⁹
- 3. In the case of NSF-sponsored research, if the inquiry will take longer than 90 days, an extension of time should be requested from the NSF.⁸⁰

X. The Inquiry Report

A. Preparing the Inquiry Report

- 1. At the conclusion of the inquiry, an inquiry report must be prepared. For research involving PHS-supported activities, the report must be provided to ORI within 30 days of determining that an investigation is warranted. The report must include the following information:
 - a. the names, professional aliases, and positions of the respondent and complainant;
 - b. a description of the allegation(s) of research misconduct;
 - a description of funding for the research involved in the inquiry. In the case of PHSsupported activities, include grant numbers, grant applications, contracts and publications listing the PHS support;
 - d. the composition of the inquiry committee, if used, including name(s), position (s) and subject matter expertise;
 - e. inventory of sequestered research records and other evidence and description of how sequestration was conducted;
 - f. transcripts of any transcribed interviews;
 - g. timeline and procedural history;
 - h. any scientific or forensic analyses conducted;
 - i. the basis for recommending that the allegation(s) warrant an investigation;
 - j. the basis on which any allegation(s) do not merit an investigation;

⁷⁹ 42 CFR §93.307

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^{80 45} CFR §689.4(b)(1)

- k. a recommendation regarding other steps to be taken, if any. If the inquiry determines that an investigation is not warranted, it may recommend other actions.
- I. any comments on the inquiry draft report by the respondent or complainant;
- m. any university actions implemented, including communications with journals or funding agencies.⁸¹
- n. All documents relied upon must be attached to the inquiry report.
- 2. For inquiries involving PHS-supported activities, Tulane must provide the following information to ORI whenever requested:
 - a. The university's policies and procedures under which the inquiry was conducted;
 - b. The research records and other evidence reviewed, and copies of all relevant documents.
 - c. The university must keep detailed documentation of inquiries to permit a later assessment, including by ORI in matters involving PHS support, of the reasons why the university decided not to investigate. In matters involving PHS support, such documentation must be retained in accordance with 42 CFR §93.318 in matters involving PHS support and, in accordance with 42 CFR §93.305(g), the university must notify ORI of any special circumstances that may exist.⁸²
- B. Notifying the Respondent and Providing Opportunity to Comment

The university must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and, in the case of PHS-supported activities, include a copy of or refer to this part and the university's policies and procedures adopted under its research integrity assurance. ⁸³ For research involving NSF Support, the respondent must be provided with access to 45 CFR §689.

^{81 42} CFR §93.307(g), §309

^{82 42} CFR §93.309 (b-d)

^{83 42} CFR §93.308(a)

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's comments to the draft inquiry report will be attached to the final inquiry report. Based on the comments, the inquiry report may be revised as appropriate before the inquiry report is finalized.

C. Notifying the Complainant and Providing Opportunity to Comment

The university is not required to notify a complainant whether the inquiry found that an investigation is warranted.⁸⁴ The university may, but is not required to, provide relevant portions of the report to a complainant for comment. If the university provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.⁸⁵

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 findings, including whether an investigation is warranted; (b) accepts any other recommendations made in the inquiry report; 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 in the inquiry report. If the deciding official rejects the findings and/or recommendations in the inquiry report, then as part of the institutional decision, the deciding official must provide a detailed written

^{84 42} CFR §93.307(f)

^{85 42} CFR §93.308

explanation and rationale for rendering a decision different from the findings in the inquiry report. Alternatively, the deciding official may return the report with a request for additional fact finding or analysis. The inquiry is complete when the deciding official makes the institutional decision.

- When NSF sponsored research is involved, the RIO will immediately notify the NSF
 OIG when the finding of an inquiry supports an Investigation.⁸⁶
- 3. The RIO will notify appropriate university officials of the deciding official's decision.

XI. Conducting 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.⁸⁷

The purpose of the investigation is to formally develop and examine a factual record by exploring the allegation in detail and examining the research record and the evidence in depth, leading to a decision whether was research misconduct was committed and, if it was, who committed the misconduct. The investigation also requires diligently pursuing all significant issues and leads discovered that are determined relevant, including any evidence of additional instances of possible research misconduct, and, continuing the investigation to completion including broadening the scope of the investigation beyond the initial allegation(s).⁸⁸

^{86 45} CFR §689.4(b)(2)

^{87 42} CFR §93.310(a)

^{88 42} CFR §93.310(i)

A. Notifying Government Agencies and University Officials

- 1. In matters involving PHS-supported activities and/or NSF funding, the RIO must notify ORI (for PHS-supported activities) 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, its attachments, and any respondent comments. Upon request, the RIO will provide the institutional policies and procedures under which the inquiry was conducted, the research records and other evidence reviewed, and copies of all relevant documents.⁸⁹
- 2. In matters moving to investigation, the RIO may notify appropriate university officials.

B. Sequestering Materials

In accordance with Section VII(A) of this policy, all research records and other evidence needed to conduct the investigation must be sequestered.⁹⁰

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. 91

^{89 42} CFR §93.309, §310(b)

⁹⁰ 42 CFR §93.305(a), §310(d)

^{91 42} CFR §93.307(d), §93.310(d)

C. 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 allegation(s) involved in the investigation. The RIO must also give the respondent written notice of any allegation(s) of research misconduct not addressed during the inquiry or in the initial notice of investigation within a reasonable amount of time after the decision is made to pursue such allegation(s). A separate inquiry may (but is not required to) be conducted regarding additional respondents added during the investigation. ⁹² If additional respondents are identified during the investigation, a good faith attempt must be made to notify them of the allegation(s) and provide an opportunity to respond in accordance with the provisions of this policy. ⁹³

D. 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. ⁹⁴ In general, the committee should consist of three members unless circumstances necessitate otherwise.

Members of the inquiry committee may serve on the investigation committee.⁹⁵ Some or all of the members of the investigation committee may be selected from outside of the university.

^{92 42} CFR §93.310(c)

^{93 42} CFR §93.310(c)

^{94 42} CFR §93.310(f)

^{95 42} CFR §93.310(f)

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 the RIO sends notice 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 a timely 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.

E. Charging the Investigation Committee

The institutional representative, in consultation with the RIO, should define the subject matter of the investigation in a written charge to the investigation committee that:

- 1. identifies the respondent;
- 2. describes the allegation(s) 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 other evidence relevant to reaching a decision on the merits of the allegation(s);⁹⁶
- 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 whether research misconduct was committed and, if so, who committed it;

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⁹⁶ 42 CFR §93.310(e)

- advises the committee that it should consider recommending administrative action based on the facts learned during the investigation, regardless of whether or not research conduct was committed;
- instructs the committee that it must interview each 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 respondent⁹⁷;
- 8. 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;98
- 9. 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 (or some other person) committed the research misconduct intentionally, knowingly, or recklessly;
- 10. 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;
- 11. 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 and/or allegations, 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;

^{97 42} CFR §93.310(g)

^{98 42} CFR §93.313(k)

- 12. informs the committee that if, in the case of PHS-supported activities, the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year time limitation through the use, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent, then the committee must determine whether such alleged use(s) should be added to the investigation as additional allegations.
- 13. 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.
- 14. 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-supported activities, 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;
- 15. advises the investigation committee that it must take all reasonable steps to ensure the confidentiality of the research misconduct proceeding;
- 16. sets forth the time for completing the investigation. 99

F. 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

⁹⁹ 42 CFR §93:103, §93:104(b)(1), §93:105(b)(2); §93:300(e), §93:310(e); §93.313(k)

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.

G. 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 other evidence relevant to reaching a decision on the merits of each allegation(s). 100
- take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical including participation of persons with appropriate expertise who do not have unresolved personal, professional, or financial conflicts of interest relevant to the investigation; ¹⁰¹
- 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. Exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview. The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the investigation. The respondent must not be present during witness interviews but must be provided with a transcript of each interview¹⁰² and
- 4. consider the prospect of additional researchers being responsible for the alleged research misconduct and, when applicable, provide notice of and an opportunity to

¹⁰⁰ 42 CFR §93.310(e)

¹⁰¹ 42 CFR §93.310(f); in the case of an investigation involving PHS support, the investigation committee members must include the participation of persons with appropriate scientific expertise

^{102 42} CFR §93.310(g)

- respond to the allegations¹⁰³; a separate investigation reports is required for each respondent;¹⁰⁴
- conduct an investigation involving multiple institutions in accordance with this policy¹⁰⁵;
- 6. pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them. 106

H. Timing for Completing the Investigation

- All aspects of the investigation should be completed within 180 days of beginning it, including conducting the investigation, preparing the draft investigation report for each respondent, and providing the draft report to each respondent for comment. In matters involving PHS-supported activities, the institutional record, the final investigation report, and decision by the deciding official must be transmitted to ORL¹⁰⁷
- 2. If the RIO determines that the investigation will not be completed within the 180-day period, then an extension may be granted. In matters involving PHS-supported activities, the RIO will submit to ORI a written request for an extension of time that includes the circumstances or issues warranting additional time. 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. ¹⁰⁸ If an investigation involving PHS-supported activities takes more than 180 to complete, the investigation report must

¹⁰³ 42 CFR §93.305(d), §310(c) and (h)

¹⁰⁴ 42 CFR §93.310(c)(3)

¹⁰⁵ 42 CFR §93.310(i)

¹⁰⁶ 42 CFR §93.310 (j)

¹⁰⁷ 42 CFR §93.311(a), §316

¹⁰⁸ 42 CFR §93.311(b) and (c)

include the reasons for exceeding the 180-day period. 109 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. 110

XII. The Investigation Report

A. Preparing the Investigation Report

The investigation committee is responsible for preparing a separate written report for each respondent in the investigation. While an investigation into multiple respondents can convene with the same investigation committee members, separate investigation reports and research misconduct determinations are required for each respondent. Each investigation report must include the following information:

- 1. the name and position of the respondent;
- 2. composition of the investigation committee including name(s), position(s), and subject matter expertise;
- 3. a description of the nature of the allegation(s) of research including any additional allegation(s) addressed during the research misconduct proceeding;
- 4. a description and documentation of the funding for the research involved in the Investigation. For 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 specific allegation(s) of research misconduct for consideration in the investigation;
- 6. inventory of sequestered research records and other evidence, except records that were not considered relied on; and a description of how any sequestration was conducted during the investigation. The inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.

110 45 CFR §689.4(b)(4)

¹⁰⁹ 42 CFR §93.311(d)

¹¹¹ 42 CFR §93.310(c)(3)

- 7. transcripts of all interviews conducted;
- 8. identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated or plagiarized material.
- 9. any scientific or forensic analysis conducted;
- the university's policies and procedures under which the investigation was conducted;
- 11. any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments;
- 12. a statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct
- 13. if the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:
 - a. identify the individual(s) who committed the research misconduct;
 - indicate whether the research misconduct was falsification, fabrication, and/or plagiarism;
 - indicate whether the research misconduct was committed intentionally, knowingly or recklessly;
 - d. state whether the other requirements for a finding of research misconduct as described in this policy, have been met;
 - e. summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent;
 - f. in matters involving PHS support, identify the specific PHS support;
 - g. identify whether any publications need correction or retraction;
- 14. if the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.

- 15. list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS federal agencies. 112
- 16. a recommendation regarding other steps to be taken, if any, including administrative action.
- B. Notifying the Complainant and Respondent and Providing Opportunity to Comment on Draft Investigation Report

1. The Respondent

- a. The RIO must give the respondent the draft investigation report and, concurrently, a copy of or supervised access to the research records and other evidence that the investigation committee considered or relied on. The respondent must submit any comments on the draft report within 30 days of receiving the draft investigation report. 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. 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-supported activities, 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. 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.

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

¹¹² 42 CFR §93.313

^{113 42} CFR §93.312

to the RIO.¹¹⁴ If the draft investigation report is emailed to the complainant, the date of receipt is considered to be the date the email is sent.

- C. Decision by the Institutional Deciding Official 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 is responsible for making a final determination of research misconduct findings. The determination must be provided in a written decision that includes:

- a. whether research misconduct was found, and if so, who committed the misconduct;
- b. a description of relevant institutional actions taken or to be taken. ¹¹⁵ 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 recommendations 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 additional fact-finding or analysis. The institutional decision must document administrative action imposed on the respondent. The investigation is completed when the deciding official issues the institutional decision.
- 2. Notifying the Respondent

The deciding official typically will make a good faith attempt to notify the respondent in writing of the investigation committee's findings and the institutional decision.

3. Notifying Government Agencies

¹¹⁴ 42 CFR §93.312(b)

^{115 42} CFR §93.314

- a. In matters involving PHS-supported activities, after the deciding official has made a final determination of research misconduct findings, the RIO will transmit the institutional record to ORI. The institutional records must be consistent with 42 CFR §93.220 and be logically organized.¹¹⁶
- b. In matters involving NSF-sponsored research, the RIO will submit the following information to NSF OIG within the 180-day period for completing the report¹¹⁷:
 - i. the final investigation report with all attachments;
 - ii. a statement of whether the university accepts the findings of the investigation report;
 - iii. a statement of whether the university found research misconduct and, if so,who committed the research misconduct; and
 - iv. a description of any planned or completed administrative action.

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. Completing the Research Misconduct Process
- 1. Inquiries and investigations will be carried through to completion and that all significant issues and credible allegations of research misconduct will be diligently pursued.
- 2. In matters involving PHS support, ORI must be notified in advance if there are plans to close a research misconduct proceeding at the assessment, inquiry or investigation stage

^{116 42} CFR §93.316

¹¹⁷ 45 CFR §689.4, §689.9

- on the basis that the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.
- 3. A respondent's admission of research misconduct must be made in writing and signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding. In matters involving PHS support, the admission must be provided to ORI before the research misconduct proceeding is closed. A statement must be provided to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability. 118

F. Retention and Custody of the Institutional Record

The RIO must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) 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 § 93.318(a).¹¹⁹

1. For PHS-supported activities, the RIO must maintain the institutional record and all sequestered evidence including physical objects regardless of whether the evidence is part of the institutional record misconduct proceeding in a secure manner for seven years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of 42 CFR 93, whichever is later, unless custody has been transferred to HHS or ORI advises otherwise in writing. On request, the RIO must transfer custody, or provide copies, to HHS of the institutional

^{118 42} CFR §93.317

^{119 42} CFR §93.318

record or any component of the institutional record and any sequestered evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding under subparts D and E of 42 CFR Part 93. 120 For research that is not federally sponsored, the RIO must keep all records of the research misconduct proceeding in a secure manner for eleven years after the later of the date on which the research misconduct proceeding concluded. 121

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 any administrative action to be taken, after consulting with the RIO and other appropriate university officials. The administrative action may include but is not limited to:

- 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(s) 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

^{120 42} CFR §93.318(b)

¹²¹ Tulane University Retention of Research Data Policy

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 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

All reasonable and practical efforts, if requested and appropriate, will be made to protect or restore the reputations of good faith complainants, witnesses, committee members, institutional representatives, respondents against whom no finding of research and others related to a research misconduct process. ¹²² Depending on the particular circumstances, the RIO should consider notifying those individuals who are aware of or involved in the research misconduct proceeding 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 be pre-approved by the deciding official in coordination with the RIO and appropriate university officials.

^{122 42} CFR §93.300(d), §304(c))