TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
GUIDELINES AND PROCEDURES FOR
RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. Scope

These guidelines and procedures are intended to be used to carry out Texas Tech University Health Sciences Center's (TTUHSC)'s responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93 and the National Science Foundation (NSF) Policy on Research Misconduct, 45 CFR 689.4. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving any individual who, at the time of the alleged research misconduct was employed by, was an agent of, or was affiliated with TTUHSC regardless of the funding source for the research activities.

These guidelines and procedures apply only to allegations of research misconduct that occurred within six years of the date TTUHSC or DHHS received the

reasons for and determination of alternate DO will be documented in the Research Integrity Officer's (RIO's) assessment report.

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

Fabrication: making up data or results and recording or reporting them.

Falsification: 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.

Good faith: as applied to a complainant or a witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness' position could have based on the information know to the complainant or witness at the time.

Inquiry: preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures outlined in this document and in 42 CFR 93.307-309; at the conclusion of an Inquiry, there is a final Inquiry Report.

Investigation: the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or a recommendation for finding of research misconduct which may include a recommendation for other appropriate actions; at the at the conclusion of an Investigation, there is a final Investigation Report.

Notice: a written communication served in person, sent by mail or its equivalent to the last knows street address, facsimile number or e-mail address of the addressee.

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

Plagiarism: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including the theft or misappropriation of intellectual property and the pprmmporty0 ( )Tj0.024 (e)4 (s)9 etd a r14 (t)20 (r)bu-4 (d) 4 (pprm)-42 (he) (d) 4 (pprmx)

Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

Research: systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments or related matters to be studied.

Research Integrity Officer (RIO): the person responsible for: (1) the Assessment; (2) overseeing Inquires and Investigations; and (3) the other responsibilities described in this policy. The Assistant Vice President for Research Integrity shall serve as the TTUHSC RIO.

Research Misconduct: 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.

Research record: the record of data or results that embody the facts resulting from the scientific inquiry, including, but not limited to, research proposals, laboratory records (both physical and electronic) progress reports, abstracts, theses, oral presentations, internal reports, journal articles and any documents and materials provided to an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent: the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation: for purposes of this policy, retaliation means an adverse action taken against a complainant, witness, or committee member by the institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

Sponsor: For purposes of these guidelines and procedures, the sponsor is the external agency or company which is providing funding for a research project.

III. Rights and Responsibilities

A. Research Integrity Officer

The Assistant Vice President for Research Integrity will generally serve as the RIO who will have primary responsibility for implementation of the institution's policies and procedures on Research Misconduct unless otherwise determined by the DO. These responsibilities include the following duties related to Research Misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of Research Misconduct;
- Receive allegations of Research Misconduct;
- In consultation with the SVPRI and/or Associate Vice President for

Research (AVPR) shall assess each allegation of Research Misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of Research Misconduct and warrants an Inquiry;

- As necessary, take interim action and notify ORI or the Sponsor, if applicable, of special circumstances, in accordance with Section IV.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of Research Misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

Inquiry: As a matter of good practice, the Complainant should be interviewed at the Inquiry stage. At the discretion of the Inquiry Committee Chair, and in

problem.

At any time, individuals at TTUHSC may have confidential discussions and consultations about concerns of possible Research Misconduct with the RIO or with the Institutional Compliance Office and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Individuals at TTUHSC are required to cooperate with the RIO and other institutional officials in the review of Allegations and the conduct of Inquiries and Investigations. All persons with knowledge, including Respondents, have an

Throughout the Research Misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the research process. In the event of such a

- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the Inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an Investigation is warranted, not to determine whether Research Misconduct definitely occurred or who was responsible;
- States that an Investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct and, (2) the Allegation may have substance, based on the committee's review during the Inquiry.
- Informs the Inquiry Committee that they are responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this policy.

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

F. Inquiry Process

The Inquiry Committee will examine relevant research records and materials. At their discretion, they may also choose interview the Complainant, the Respondent, and/or key witnesses. Then the Inquiry Committee will evaluate the evidence, including any testimony obtained during the Inquiry. After consultation with the RIO, the committee members will decide whether an Investigation is warranted based on the criteria in this policy. The scope of the Inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the Research Misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of Research Misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, the DO shall be notified and the RIO shall promptly consult with ORI and the Sponsor, if one exists, to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The Inquiry, including preparation of the final Inquiry Report and the decision of the DO on whether an Investigation is warranted, must be completed within 60 calendar days of the appointment of the Inquiry Committee members, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 60-day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written Inquiry Report must be prepared by the chairperson of the Inquiry Committee. The report will include the following information: (1) the names and titles of the committee members (2) the name and position of the Respondent; (3) a description of the allegations of Research Misconduct; (4) the funding agency, if applicable, including, for example, grant numbers, grant applications, contracts and publications; (5) a list of the research records reviewed; (5) the basis for recommending or not recommending that the allegations warrant an Investigation; (6) any other actions which are recommended if an Investigation is not recommended; and (7) any comments on the draft report by the Respondent or Complainant.

The RIO, in consultation with the Inquiry Committee Chair and DO, may request the Office of General Counsel to review the Inquiry Report. Recommended modifications will be discussed with the RIO and the Inquiry Committee Chairperson.

B. Notification to the Respondent and Opportunity to Comment

If the Inquiry Committee has determined that it is appropriate to provide a draft of

secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

C. Appointment of the Investigation Committee

The Deciding Official will appoint an Investigation Committee and the committee chair as soon after the beginning of the Investigation as is practical. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial Conflicts of Interest v238 Tc tfr o, oENve v238 as28 Tc 09e I

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2. First Meeting

The RIO will convene the first meeting of the Investigation Committee to review the charge, the Inquiry Report, and the prescribed procedures and standards for the conduct of the I

draft report of the Investigation that:

- Describes the nature of the Allegation of Research Misconduct, including identification of the Respondent;
- Describes and documents the research funding, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications;
- Describes the specific Allegations of Research Misconduct considered in the Investigation;
- Includes the institutional policies and procedures under which the Investigation was conducted, unless those policies and procedures were provided to ORI and Sponsor (if any) previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed;
- Documents the DO's determination that an Investigation was warranted based on the Inquiry Committee's findings;
- Includes a statement of findings for each allegation of Research Misconduct identified during the Investigation. Each statement of findings must: (1) identify whether the Research Misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in Research Misconduct because of honest error or a difference of opinion; (3) identify the specific research support received; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the Respondent has pending with any funding agency.

B. Comments on the Draft Investigation Report and Access to Evidence

1. Respondent

The RIO must give the Respondent a copy of the draft Investigation Report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The Respondent's comments must be included and considered in the final report.

2. Complainant

The Complainant will be provided a copy of the draft Investigation Report, or relevant portions of it, for comment. The Investigation Committee Chair will make a determination as to whether the Complainant will receive a copy of the draft report or relevant portions of it. The Complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be

included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent (and Complainant, when relevant) the RIO will inform the recipient(s) of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official

The RIO will assist the Investigation Committee in finalizing the draft Investigation Report which may include the Respondent's and Complainant's comments and written consideration of those comments, and transmit the final Investigation Report to the DO, who will determine in writing: (1) whether TTUHSC accepts the Investigation Report, its findings, and the recommended institutional actions; and (2) the appropriate actions to be taken in response to the accepted findings of Research Misconduct. If this determination varies from the findings of the Investigation Committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis.

When the DO issues a final written decision on the case, the RIO will notify both the Respondent and the Complainant in writing. After informing ORI and the Sponsor, if any, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO will assist the DO with all notification requirements.

D. Notice to ORI and Sponsoring Agency of Institutional Findings and Actions

Unless an extension has been granted, the RIO, in co-operation with the DO must, within the 120-day period for completing the Investigation, submit the following to ORI and Sponsor: (1) a copy of the final Investigation Report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the Investigation Report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.

F. Maintaining Records for Review by ORI and Sponsor

The RIO must maintain and provide to ORI and Sponsor, if any, upon request, all records of Research Misconduct proceedings. Unless custody has been transferred to a funding agency or ORI has advised in writing that the records no

longer need to be retained, records of Research Misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any Sponsor's proceeding involving the Research Misconduct Allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or the Sponsor to carry out its review of an Allegation of Research Misconduct or of the institution's handling of such an Allegation.

IX. Completion of Cases; Reporting Premature Closures

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI or the Sponsor in advance if there are plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except: (1) closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no misconduct at the Investigation stage, which must be reported to ORI or the Sponsor.

X. Institutional Administrative Actions

If the DO determines that Research Misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO and other TTUHSC administrators. The administrative actions may include:

- Retraction, withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the Research Misconduct.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's employment with TTUHSC, by resignation or otherwise, before or after an Allegation of possible Research Misconduct has been reported, will not preclude or terminate the Research Misconduct proceeding or otherwise limit any of TTUHSC's responsibilities under this policy.

If the Respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an Allegation of Research Misconduct, the assessment of the Allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and any

Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning the Allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a report finding no Research Misconduct, including ORI and Sponsor (if any) concurrence where required, the RIO must, at the request of the Respondent, undertake all reasonable and appropriate efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent, the RIO should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the Allegation of Research Misconduct was previously publicized, and expunging all reference to the Research Misconduct Allegation from the Respondent's personnel file. Any institutional actions to restore the Respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the Research Misconduct proceeding and upon its completion, regardless of whether the institution, ORI or the Sponsor determines that Research Misconduct occurred, the RIO must undertake all reasonable and appropriate efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made Allegations of Research Misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the Research Misconduct proceeding. The DO will determine, after consulting with the RIO, and with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for facilitating implementation of any steps the DO approved.

D. Allegations Not Made in Good Faith

At any stage, in the DO’s sole discretion, he or she may make a determination whether the Complainant’s allegations of Research Misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.