

Texas Woman's University

Procedures for Responding to Allegations of Research Misconduct

I. INTRODUCTION

A. Statement of Commitment

Texas Woman's University (TWU) encourages and maintains the highest ethical standards in research. TWU is responsible for the prevention, detection, and investigation of research misconduct and shall take action to ensure the integrity of research, the protection of the rights of research subjects and the public, the protection of the health and safety of the public, and the observance of legal requirements related to all research funding. The purpose of this document is to establish procedures for responding to research misconduct allegations in a thorough, competent, and fair manner and in accordance with the governing TWU policy.

The following procedures for responding to allegations of research misconduct are intended to comply with the research misconduct requirements of the Federal Research Misconduct Policy, the U.S. Public Health Service (PHS) (42 CFR Part 93), and any other applicable research misconduct requirements of agencies or entities providing research funding to TWU. These procedures apply only to allegations of research misconduct that occurred within six years of the date TWU received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

B. Scope

This document applies to allegations of research misconduct involving:

1. a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with TWU; and
2. research, research training, or activities related to that research or research training;
3. applications or proposals for research training or activities related to that research or research training; or
4. plagiarism of research records produced in the course of research training or activities related to that research or research training; or
5. any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether funding for the research was sought from any source.

This document does not apply to the following types of inappropriate research behaviors per the US Department of Health and Human Services Office of Research Integrity (ORI):

- Misuse of human or animal subjects
- Misconduct and other complaints involving FDA-regulated research

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- Financial mismanagement
- Radiation or biosafety hazards
- Conflicts of interest
- Problem areas associated with the research process that fall largely within the responsibility of institutions and scientific and professional associations
 - Authorship responsibilities
 - Collaboration agreements
 - Data Sharing
 - Duplicate publication
 - Laboratory Management
 - Quality Control
- Certain types of falsifications in clinical trials fall under the jurisdiction of the Institutional Review Board per the US Department of Health and Human Services ORI.
 - Falsified or forged consent forms
 - Failure to report an adverse event to the IRB or sponsor
 - Protocol deviations such as entering ineligible subjects, administering an off-protocol drug, or forging a physician's signature on orders
 - Failure to obtain informed consent
 - Breach of patient confidentiality
 - Failure to obtain IRB approval for changes to protocol
- Fabrication, falsification, or plagiarism in activities that do not fall within the definition of research per the TWU Research Misconduct Policy or this document (Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop generalizations, principles, or theories that contribute to broader knowledge or understanding of the subject studied).

C. Definition of Research Misconduct

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Research misconduct is defined as fabrication, falsification, or plagiarism (including self-plagiarism) in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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- Research misconduct does not include honest errors or differences of opinion.

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community,
- The misconduct be committed intentionally, knowingly, or recklessly, and
- The allegation be proven by a preponderance of the evidence.

II. GENERAL DEFINITIONS

Allegation means any written or oral statement of possible research misconduct made to an institutional official. Applicable dean means the dean of the academic college with which the respondent in allegations of research misconduct is associated.

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

Conflict of Interest, as used in this URP, means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

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

Good faith allegation means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with knowing or reckless disregard for facts that would negate the allegation or testimony.

Inquiry means preliminary gathering of information and fact-finding to determine whether an allegation of apparent instance of research misconduct warrants an investigation. Institutional member means a person who is employed by, is an agent of, or is affiliated by contract or agreement with TWU. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, contractors, subcontractors, and sub-awardees, and their employees.

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

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

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

PHS means the U.S. Public Health Service, an operating component of the DHHS

PHS regulations means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 93, entitled "Public Health Service Policies on Research Misconduct."

PHS support means PHS grants, contracts, or cooperative agreements or applications/proposals for same.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Provost is the chief academic officer of TWU who oversees all matters related to academic programs at TWU and also serves as the deciding official during research misconduct proceedings.

Records of research misconduct proceedings comprise the following:

1. The research records and evidence secured for the research misconduct proceeding pursuant to this procedure, including any records provided by any involved funding entity, except to the extent that the individual(s) conducting the inquiry or investigation as applicable determine and document that those records are not relevant to the proceeding or that the records duplicate other records that have been retained;
2. The documentation of the determination of irrelevant or duplicate records;
3. The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; and
4. The investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted.

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Research Integrity Officer (RIO) means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer is also the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Vice Provost for Research and Innovation or his or her designee, will serve as the Research Integrity Officer.

Research misconduct is defined as fabrication, falsification, or plagiarism (including self-plagiarism) in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
 - Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest errors or honest differences of opinion or interpretations of data. Research record means the record of data or results that embodies the facts resulting from 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 the relevant office of any involved funding entity or an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent means the person or persons against whom an allegation of research misconduct is directed or who is the subject of the inquiry or investigation. There can be more than one Respondent in any inquiry or investigation. Retaliation means any adverse action taken against an individual in response to a good faith allegation of research misconduct, or good faith cooperation with research misconduct proceedings of the University.

Self-Plagiarism is the reuse of significant, identical, or nearly identical portions of one's own work without acknowledging that one is doing so or citing the original work.

Vice President for Student Life is responsible for issues concerning students including oversight of academic dishonesty disciplinary proceedings.

Responsibility to Report Misconduct

All TWU members shall report observed, suspected, or apparent research misconduct to the Vice Provost for Research and Innovation/Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with the responsibility for resolving the problem. Any TWU official who receives an allegation of research misconduct must report it immediately to the Vice Provost for Research and Innovation.

Protecting the Complainant

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will make reasonable and practical efforts to counter potential and or actual retaliation against these persons in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer. Also the institution will protect the privacy of those who report misconduct in good faith to the extent practicable. For example, if the Complainant requests anonymity, the institution will make an effort to honor the request in accordance with applicable policies and regulations and state and local laws. TWU will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s) in thoroughly carrying out the inquiry or investigation, and confidentiality to the extent possible without compromising public health and safety. Respondents accused of research misconduct may consult with legal counsel, or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the case with advance notice to the inquiry/investigation committee.

RIGHTS AND RESPONSIBILITIES

Research Integrity Officer

The Research Integrity Officer will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith. At TWU, the Research Integrity Officer is the Vice President for Research and Innovation or her/his designee. The Research Integrity Officer will:

- appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation.
- attempt to ensure that confidentiality is maintained.
- assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources.

- be responsible for securing and maintaining the confidentiality of all documents and evidence.
- report to external sponsors of research, as required by regulation.
- receive the inquiry and/or investigation report and any written comments made by the Respondent on the draft report.
- consult with other officials as appropriate and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate actions.

Complainant

The Complainant may have an opportunity to testify before the inquiry and investigation committees and be informed of the results of the inquiry and investigation, and to be protected from retaliation. The Complainant is responsible for making allegations in good faith and cooperating, in good faith, with an inquiry or investigation.

Respondent

The Respondent will be informed of the allegations prior to or when an inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel. The Respondent is responsible for cooperating with the conduct of an inquiry or investigation. If the Respondent is not found to have committed research misconduct, he or she has the right to receive institutional assistance in restoring her or his reputation.

CONDUCTING THE ASSESSMENT

Upon receiving an allegation of research misconduct, the Research Integrity Officer will assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether external sponsors are involved, and whether the allegation falls under the definitions of research misconduct contained in this Policy. If the RIO determines that the allegation is groundless, he or she shall prepare and maintain a memorandum separate from the respondent's personnel review file and shall inform the complainant of the decision not to proceed. In such a case, the respondent does not need to be informed of the allegation.

CONDUCTING THE INQUIRY

Initiation and Purpose of the Inquiry

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Following the preliminary assessment, if the Research Integrity Officer determines that the allegation is sufficiently credible and specific so that potential evidence or research misconduct may be identified and the allegation falls under the definitions of research misconduct contained in this Policy, he or she will initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should clearly identify the original allegation and make appropriate referrals to other office and/or committees for concerns that fall outside the definition of research misconduct. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible, but is a process of gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation. An investigation is warranted if there is (1) a reasonable basis for concluding that the allegation falls within the definition of research misconduct, and (2) preliminary information gathering and preliminary fact finding from the inquiry indicates that the allegation may have substance.

Maintenance and Custody of the Research Records

To the extent not already done so at the allegation stage, after determining an allegation falls within the definition of research misconduct, the Research Integrity Officer will take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceedings. The Research Integrity Officer will immediately sequester any additional pertinent research records. The sequestration should occur before or at the time the Respondent is notified that an inquiry has begun. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, or other qualified persons, and they may be from inside or outside the institution. The inquiry committee may solicit expert consultation from an outside party (e.g., scientific expert, forensic expert, etc.) as needed. The Research Integrity Officer will notify the Respondent of the proposed committee membership within ten (10) days of its appointment. If the Respondent submits a written objection to any appointed member of the inquiry committee or expert, based on a conflict of interest, within five (5) business days, the Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute.

Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a written charge for the inquiry committee that describes the allegations and states that the purpose of the inquiry is to make a preliminary evaluation of evidence and testimony to determine whether there is sufficient evidence of possible research misconduct to

warrant an investigation. At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, and orient the committee to the relevant regulations and procedures. The Office of the Vice Provost for Research and Innovation will provide administrative support to the committee throughout the proceedings. The Vice Provost for Research and Innovation/Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

Inquiry Process

The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. Based on the evidence reviewed, the committee will decide whether there is sufficient evidence of possible research misconduct to recommend that an investigation be conducted. The scope of the inquiry does not, necessarily, include deciding whether misconduct occurred or a full review of all the evidence related to the allegation.

THE INQUIRY REPORT

Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the respondent; the name and title of the committee members and experts, if any; the allegations; external sponsor support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is recommended by the inquiry committee and whether any other action should be taken if an investigation is not recommended; comments on the report by the respondent. Institutional counsel may review the report for legal sufficiency. The inquiry report should follow the format of the *TWU Investigation Report template* provided at the end of this document.

Comments on the Draft Report

The Research Integrity Officer will make available to the Respondent a copy of the draft inquiry report for comment and rebuttal. Any comments received will be attached to the report for consideration by the inquiry committee and appended to the report when provided to the Research Integrity Officer for final determination. The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report. Within ten (10) calendar days of her/his receipt of the draft report, the Respondent will provide her/his comments, if any, to the inquiry committee. Comments that the Respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise its report as appropriate.

Inquiry Decision and Notification

The Research Integrity Officer will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is

completed when the Research Integrity Officer makes this determination, which will be made within sixty (60) days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file. The Research Integrity Officer will notify both the Respondent and the Complainant in writing of the decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. In the case of the respondent a copy of the final inquiry report will be provided. The Research Integrity Officer will also notify all appropriate institutional officials and, where appropriate, the research sponsor(s) of the decision.

Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than sixty (60) calendar days following its first meeting, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report.

CONDUCTING THE INVESTIGATION

Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are individual instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

Sequestration of the Research Records

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. The sequestration should occur before or at the time the Respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee within thirty (30) days after determining that an investigation is warranted. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the key principles and witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, or other qualified persons, and they may be from inside or outside the institution. The investigation committee may solicit expert consultation from an outside party (e.g., scientific expert, forensic expert, etc.) as needed. Individuals appointed to the investigation committee may also have served in the inquiry committee. The Research Integrity Officer will notify the Respondent of the proposed committee membership within five (5) days of its appointment. If the Respondent submits a written objection to any appointed member of the investigations committee or expert, the Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute.

Charge to the Committee and the First Meeting

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations identified during the inquiry; defines research misconduct; and identifies the Respondent(s). The charge will state that the committee is to evaluate the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the investigation, if the Committee uncovers evidence that warrants new or revised allegations or implicates additional Respondent(s), the Committee will notify the Research Integrity Officer. The Research Integrity Officer will preliminarily assess the new evidence and provide notice to the Respondent and/or additional Respondents when required.

The Research Integrity Officer, with possible assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality. The investigation committee will be provided with a copy of these instructions and, where external sponsors' funding is involved, the sponsors' regulation.

Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation. The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the Complainant(s), the Respondent(s), and other individuals who might

have information regarding aspects of the allegations. All interviews should be tape recorded, or transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or suggested revision, and included as part of the investigatory file.

THE INVESTIGATION REPORT

Elements of the Investigation Report

The final report will be submitted to the external sponsor, if any, and will: describe the allegations; describe sources of external funding, if any; describe the specific allegations of research misconduct considered in the investigation; describe the policies and procedures under which the investigation was conducted; describe how and from whom information relevant to the investigation was obtained; state the findings; and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution. The report will be submitted using the *TWU Investigation Report Template* provided at the end of this document.

Comments on the Draft Report

The Research Integrity Officer will provide the Respondent with a copy of the draft investigation report for comment or rebuttal. The Respondent will be allowed thirty (30) days to review and comment on the draft report. The Respondent's comments will be attached to the final report. The findings of the final report should take into account the Respondent's comments in addition to all the other evidence. The draft investigation report may be transmitted, as deemed necessary and appropriate, to institutional counsel for a review of its legal sufficiency. Comments of the counsel will be incorporated into the report as appropriate.

In distributing the draft report, or portions thereof, to the Respondent, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to her/his office to review the report.

Institutional Review and Decision

Based on a preponderance of the evidence, the Research Integrity Officer will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Research Integrity Officer will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to any external sponsors. The Research Integrity Officer's explanation should be consistent with the federal definitions of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Research Integrity Officer may also return the report to the investigation

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committee with a request for further fact-finding or analysis. The Research Integrity Officer's determination, together with the investigation committee's report, constitutes the final investigation report for the purposes of external sponsor review. When a final decision on the case has been reached, the Research Integrity Officer will notify both the Respondent and the Complainant in writing. In addition, the Research Integrity Officer will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified/fabricated/plagiarized 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

Transmittal of the Final Investigation Report

After comments have been received and any necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the Respondent's comments, to the Research Integrity Officer. The Research Integrity Officer shall transmit a copy of the investigation report with attachments to any external sponsors as required.

Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within one hundred twenty (120) days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of the findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Research Integrity Officer for approval, and submitting the report to the appropriate regulatory agency when required. If the Research Integrity Officer approves an extension for good cause, the reason for the extension will be entered into the records of the case and the report.

REQUIREMENTS FOR CASES INVOLVING PHS FUNDING

An institution's decision to initiate an investigation must be reported in writing to the Director, federal Office of Research Integrity, on or before the date the investigation begins. At minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

If an institution plans to terminate an inquiry for any reason other than that an investigation is not warranted or an investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

If the institution determines that it will not be able to complete the investigation in one hundred twenty (120) days, the Research Integrity Officer will submit to ORI a written request for extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

1. there is an immediate health or safety hazard involved, including the immediate need to protect human or animal subjects; or
2. there is an immediate need to protect Federal funds or equipment; or
3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as her/his co-investigators and associates, if any; or
4. It is probable that the alleged incident is going to be reported publicly; or
5. the research activities should be suspended; or
6. there is reasonable indication of possible violation of civil or criminal law. In this instance, the institution must inform ORI immediately after obtaining that information.

INSTITUTIONAL ADMINISTRATIVE ACTIONS

Texas Woman's University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the Research Integrity Officer determines that the alleged misconduct is substantiated by the findings, he or she will decide, in consultation with other institutional parties as needed, on the appropriate actions to be taken. The actions may include but are not limited to:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- removal of the responsible person from the particular project;
- letter of reprimand; special monitoring of future work; probation; suspension;

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- salary reduction;
- initiation of steps leading to possible rank reduction or termination of employment; or restitution of funds as appropriate.

OTHER CONSIDERATIONS

Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures. If the Respondent, without admitting to the misconduct, elects to resign her or his position prior to the initiation of the inquiry, but after an allegation has been made, or during an inquiry or investigation, the inquiry or investigation will proceed. If the Respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

Restoration of the Respondent's Reputation

If the institution finds no misconduct, after consulting with the Respondent as needed, the Research Integrity Officer will undertake reasonable efforts to restore the Respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer may consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Research Integrity Officer.

Protection of the Complainant and Others

Regardless of whether the institution determines that research misconduct occurred, the Research Integrity Officer will make reasonable efforts to protect Complainants who made allegations of research misconduct in good faith and any individuals who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Research Integrity Officer will determine, after consulting with the Complainant as needed, what steps, if any, are needed to restore the position or reputation of the Complainant. The Research Integrity Officer is responsible for implementing any such steps. The Research Integrity Officer will also make reasonable efforts during the inquiry and investigation to prevent any retaliation against the Complainant.

Allegations Not Made in Good Faith

If relevant, the Research Integrity Officer will determine whether the Complainant's allegations of research misconduct were made in good faith. If a determination is made that an allegation was not

made in good faith, the Research Integrity Officer will determine whether any administrative action should be taken against the Complainant.

Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect external sponsors' funds and, if Federal funds are involved, ensure that the purposes of the Federal financial assistance are carried out.

RECORD RETENTION

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven (7) years beyond completion of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

DELEGATION OF AUTHORITY AND RESPONSIBILITY

A. Provost

The Provost shall make all final determinations on research misconduct findings involving faculty and staff members.

B. Dean of Applicable College

The Provost delegates to the applicable dean (dean of the College with which the respondent is associated) authority and responsibility for

1. fostering a research environment that discourages misconduct in all research;
2. taking all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made;
3. taking all reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members.

C. Vice Provost for Research and Innovation

The Provost delegates to the Vice Provost for Research and Innovation the authority to serve as the Research Integrity Officer. This confers the authority to review research misconduct inquiry reports and

make decisions regarding the initiation of a research misconduct investigation. The Provost also delegates to the Vice Provost for Research and Innovation responsibility for

1. fostering a research environment that discourages misconduct in all research.
2. implementation, dissemination, and maintenance of policies, procedures, and records related to misconduct in research;
3. assessment of each allegation to determine whether it falls within the definition of research misconduct and warrants an inquiry;
4. notification, as necessary or required, to institutional officials and to parties involved in research misconduct proceedings including the respondent and the complainant;
5. maintenance of confidentiality of records, in accord with established University policy, relating to the investigation and resolution of incidents of misconduct in research;
6. notice to involved funding agencies of any facts that may be relevant to protect public health, research funds and equipment, or the integrity of any research process;
7. if external funds are involved, determining whether law, regulation, or the terms or conditions of the award
 - a. require notification of the sponsor;
 - b. specify time limits; or
 - c. require other actions to assure compliance.
8. maintenance of records of the research misconduct proceeding and, in accordance with any federal, state or other applicable requirements, make them available to the relevant office of any funding entity.

NOTE: The Vice Provost for Research and Innovation, who is responsible for the maintenance of records and all reporting requirements, should receive copies of all external and internal correspondence and documentation.

IV. GENERAL PRINCIPLES AND PROCEDURES

A. Responsibility to Report

All individuals associated with TWU shall report observed, suspected, or apparent research misconduct to the Vice Provost for Research and Innovation or via the TWU Compliance Hotline. Any report made through the TWU Compliance Hotline will ultimately be routed to the Vice Provost for Research and Innovation. An allegation should, in addition to stating the nature of the suspected misconduct, present evidence that leads the reporting individual to believe that an incident of research misconduct has

occurred. Any TWU official who receives an allegation of research misconduct shall take no action other than to report it immediately to the Vice Provost for Research and Innovation. It is the responsibility of the Vice Provost for Research and Innovation to determine whether an allegation appears to fall within the definition of “research misconduct.” If the Vice Provost for Research and Innovation determines it does not fall within the definition, she/he may refer the person making the report to other appropriate policies or TWU personnel (e.g., Policy 3.01 Professional Ethics).

B. Confidentiality

Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, in order to carry out a thorough, competent, objective, and fair proceeding. To the extent reasonably possible or except as may otherwise be prescribed by law, confidentiality must be maintained for any records or evidence from which research subjects might be identified; and disclosure is limited to those who need to know.

C. Special Circumstances

If the research at issue receives or has received federal funding, and, at any point during an inquiry or subsequent investigation, it is ascertained that any of the following conditions pertain, the Vice Provost for Research and Innovation will immediately notify the sponsoring federal agency:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
7. The research community or public should be informed.
 - I. The Provost 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.
 - J. The Vice Provost for Research and Innovation must maintain and, in accordance with federal, state, and local requirements, provide to the relevant office of any involved funding entity upon request

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“records of research misconduct proceedings” as that term is defined by the applicable regulations of any involved funding entity. Records of research misconduct proceedings must be maintained in a secure manner for at least 7 years after completion of the proceeding or the completion of any funding entity proceeding involving the research misconduct allegation or for the applicable retention period under the TWU records retention schedule, whichever is longer. The Vice Provost for Research and Innovation is also responsible for providing any information, documentation, research records, evidence, or clarification requested by the funding entity, as allowed by law or regulation, to carry out its review of an allegation of research misconduct or of TWU’s handling of such an allegation.

VIII. OTHER CONSIDERATIONS

If the respondent, without admitting to the misconduct, elects to resign her or his position after TWU 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 applicable dean and the individual(s) appointed to conduct research misconduct inquiries or investigations 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.

If the respondent admits to the misconduct after TWU 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.

[LETTERHEAD]

Investigative Report

Month, day, Year

Parties:

Complainant
Name
Title/Student

Respondent
Name
Title/Student

Investigator
Name

Initiation of Investigation:

The initiation of investigation provides context for the investigation and explains why the particular office is conducting the investigation. It details actions related to the complainant or the complaint that occurred prior to the matter reaching the investigating office; identifies any activities taken by the investigating office prior to investigating the complaint; and provides information necessary to establish why the office conducting the investigation has jurisdiction over the matter; including naming the policy that establishes jurisdiction.

Example:

On April 1, 2018, Jane Complainant (Coordinator, Best Ever Department) filed a complaint with Human Resources alleging that her former supervisor John Respondent (Director, Best Ever Department) discriminated against her on the basis of sex and age. Specifically, Ms. Complainant alleged that she was not promoted within the unit because she is a female and over the age of 40. Human Resources initiated an investigation on April 10, 2018.

Allegations:

The allegations describe each allegation as succinctly and clearly as possible and identifies the policy or policies that would be violated if the allegation were found to be true.

Example:

1. *[Dr./Mr./Ms. Last Name of Respondent] engaged in [specific prohibited conduct – discrimination/harassment on the basis of [protected class]/sexual harassment/retaliation/other] when [what event is alleged to be discriminatory] in violation of TWU [Policy or URP that is implicated].*

2. *Mr. Respondent engaged in discrimination on the basis of sex and age when he failed to promote Ms. Complainant in violation of TWU [Policy or URP that is implicated].*

Investigation Findings:

The investigation findings provides a determination of the outcome of the investigation and describes succinctly how the investigator arrived at its finding.

Example:

1. *There is **sufficient/insufficient** evidence to substantiate the allegation that [Dr./Mr./Ms. Last Name of Respondent] engaged in [specific prohibited conduct – discrimination/harassment on the basis of [protected class]/sexual harassment/retaliation/other] when [what event is alleged to be discriminatory/harassing/retaliatory/other] in violation of TWU [Policy or URP that is implicated]. **Provide a brief rationale as to why the investigation findings were substantiated or unsubstantiated.***
2. *There is insufficient evidence to substantiate the allegation that Mr. Respondent engaged in discrimination on the basis of sex and age when he failed to promote Ms. Complainant in violation of TWU [Policy or URP that is implicated]. Human Resources verified that Ms. Complainant failed to apply for any promotion at TWU and was not qualified for the Executive Director position she sought to attain.*

Interviews:

[Complainant's Name] Interview

Insert synthesized version of interview.

[Witness Name/Student 1] Interview

Insert synthesized version of interview.

[Witness Name/Student 2] Interview

Insert synthesized version of interview.

[Respondent's Name] Interview

Insert synthesized version of interview.

Documents Review/Other Consideration: [If Applicable]

Insert documents reviewed.

Insert other considerations investigator relied upon.

Findings of Fact:

The findings of fact sets out all facts that are necessary and relevant to the analysis and determination of the investigation. Necessary and relevant facts are those relied upon in making a determination as well as facts from which any reasonable inferences are drawn in making a determination. Facts must be presented in a logical sequence, such as chronologically or by subject matter.

The findings of fact are critically important when drafting an investigative report. Facts developed by a thoroughly investigated case speak for themselves. Every factual finding should be supported by a document or a documented statement from a one of the parties or witness.

Example:

- *Ms. Complainant did not apply for any vacant positions within her unit or elsewhere at TWU.*
- *Ms. Complainant was trained and offered an Assistant Director position; however she declined the position.*
- *Ms. Complainant did not have the qualifications necessary for the vacant Executive Director position.*

Analysis and Determination:

States whether a policy violation occurred and explains how the investigator reached this conclusion using a preponderance of the evidence standard. Facts standing alone do not prove or disprove a policy violation. In this section, the investigator applies the facts to the allegations and applicable policy using documents, corroborated and/or uncorroborated witness testimony, or other independent sources of information to determine the veracity of each allegation. Each conclusion, comparison, inference, and general statement must be drawn from a fact or facts developed during the investigation.

The sole focus of the determination is whether the facts and reasonable inferences drawn from the facts support the allegations. Other matters that do not fall within the investigating office's jurisdiction or that are unrelated to the allegations should not be mentioned in the investigative report. These matters and concerns may be brought to the attention of the appropriate official, preferably in a face-to-face meeting. Investigators should not reach conclusions or express opinions about matters that are outside their area of responsibility, including conclusions or

opinions concerning the prudence of personnel, administrative, operational, or financial decisions.

All analysis and determination should follow the McDonnell Douglas rubric. Specifically, the analysis should determine whether the facts support a prima facie case of discrimination or harassment, whether the respondent articulated a legitimate nondiscriminatory reason to rebut the prima facie case, and whether there are facts that overcome the reason articulated for the action.

In all retaliation cases, the analysis should determine whether the complainant engaged in protected activity; whether adverse action was taken against the employee after engaging in the activity; and whether there is a causal connection between engaging in the protected activity and the adverse action.

Example:

Texas Woman's University's [Name of Policy or URP] states [identify anti-discrimination/harassment/retaliation provision].

There is insufficient evidence to substantiate the allegation that Mr. Respondent engaged in discrimination on the basis of sex and age when he did not promote Ms. Complainant in violation of TWU [Name of policy or URP]. Ms. Complainant alleged that Mr. Respondent did not promote her because of her sex and age. However, Human Resources established that Ms. Complainant failed to apply for any promotions and refused a position that was offered to her. Human Resources also established that Ms. Complainant was not qualified for the position of Executive Director she sought to attain without having to go through the hiring and selection process. Based on the foregoing, Human Resources was unable to substantiate Ms. Complainant's claim.

Conclusion:

This section should restate the finding and identify what happens as next steps in the process.

Proposed Corrective/Remedial Action (Under Separate Cover):

This section describes the action(s) the investigator recommends the respondent take to correct or remediate the policy violation, including actions necessary to make the complainant whole, and action(s) necessary to reduce the occurrence of future violations. Recommendations should pertain only to correcting violations of policies that are within the investigating office's jurisdiction. Further, before making a recommendation, the investigator should ensure the action is legally permissible.

