

I. Introduction

This guidance provides information regarding suggested best practices related to the Research Integrity Officer's responsibilities related to Research Integrity at Texas Christian University ("TCU"). While this document offers an overview of the responsibility of the TCU Research Integrity Officer ("RIO"), it is not controlling and is provided for information purposes only. In the event of any conflict or inconsistency between this guidance and TCU's Research Integrity policy and procedures, the policy and procedures control. All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

The RIO, or the RIO delegate, has primary responsibility for implementation of TCU policies and procedures on Research Integrity, and overseeing all related proceedings, including lead responsibility for helping to ensure that TCU:

I. General

- Takes reasonable and practical steps to foster a research environment that promotes Research Integrity; discourages research misconduct and other research activities that deviate from accepted practices in the research community or do not comply with TCU policies and procedures, or applicable law ("Research Integrity Violation"), and deals promptly with allegations or evidence of research misconduct or Research Integrity Violation.
- Leads inquiries and investigations into allegations or evidence of Research Misconduct and Research Integrity Violation.
- Has written policies and procedures regarding research at TCU, including for responding to allegations of research misconduct and reporting information about that response to ORI
- Complies with its written policies and procedures and applicable law, including the requirements of 42 CFR Part 93.
- Makes its research policies and procedures available to its institutional members who are subject to such policies and procedures through the Office of Research's website.
- Informs of its commitment to compliance with those policies and procedures through various outlets, including the Office of Research's website.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

- Files an annual report with ORI, as well as any other information required by ORI regarding research misconduct.
- Notifies ORI immediately if it has reason to believe that: (1) health or safety of the public is at risk, (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) TCU believes that the research misconduct proceeding may be made public prematurely, or (7) the research community or the public should be informed.
- Provides ORI with the written finding that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.
- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.
- Within 120 days of beginning an investigation, or such additional days as may be granted by ORI, provides ORI with the investigation report, a statement of whether TCU accepts the investigation's findings, a statement of whether TCU found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- Seeks advance ORI approval if TCU plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.
- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under TCU's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

- Promptly takes all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.
- Takes all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

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- Provides confidentiality to those involved in the research misconduct proceeding as required by applicable law, and institutional policy.
- Determines whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and takes appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeps the DO and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- Takes all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.
- Makes 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.
- Implements the decision to take administrative action against any Complainant, witness, or committee member determined not to have acted in good faith.
- Maintains records of the proceeding in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the Allegation, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
- Ensures that administrative actions taken by TCU and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

- Consults confidentially with persons uncertain about whether to submit an Allegation.
- Receives Allegations.
- Assesses each Allegation to determine if an Inquiry is warranted.

C. Inquiry

- Initiates the Inquiry process, if determined warranted.

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- At the time of, or before beginning the Inquiry, makes a good faith effort to notify the Respondent in writing, if the Respondent is known.
- On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, takes all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the proceeding, inventories the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Appoints an Inquiry committee and committee chair as soon after the initiation of the inquiry as is practical, if the RIO determines an inquiry committee is necessary.
- Prepares a charge for the Inquiry committee.
- Convenes the first meeting of the Inquiry committee and, at that meeting, briefs the committee on the Allegations, the charge to the committee, and the appropriate procedures for conducting the Inquiry, including the need for confidentiality and for developing a plan for the Inquiry, and assists the committee with any issues that may arise.
- Provides the Inquiry committee with any needed support, including expert advice, forensic analysis of evidence, and clerical support.
- Is available throughout the Inquiry to advise the committee as needed and consults with the committee prior to its decision on whether to recommend that an investigation is warranted.
- Determines whether circumstances clearly warrant a period longer than 60 days to complete the Inquiry, approving an extension if warranted, and documents the reasons for exceeding the 60-day period in the record of the proceeding.
- Assists the Inquiry committee in preparing a draft Inquiry report, sends the Respondent a copy of the draft report for comment within a time that permits the Inquiry to be completed within the allotted time, takes appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent, and ensuring that the comments are attached to the final Inquiry report.
- Receives the final Inquiry report from the Inquiry committee and provides it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an Investigation is warranted.
- Within 30 days of a DO decision that an investigation is warranted, provides ORI or other regulatory agency, as required, with the written finding and a copy of the Inquiry report and notifies those institutional officials who need to know of the decision.

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- Notifies the Respondent whether the Inquiry found an Investigation to be warranted and, if Allegation involves Research Misconduct, includes in the notice a reference to 42 CFR Part 93 and TCU's Research Integrity policies and procedures.
- Providing to ORI, upon request, the TCU policies and procedures under which the Inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the Allegations to be considered in the Investigation.
- If an Investigation is not warranted, secures and maintains for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI.

D. Investigation

- Initiates the Investigation within 30 calendar days after the determination that an Investigation is warranted.
- On or before the date on which the Investigation begins: (1) notifies ORI of the decision to begin the Investigation and providing ORI a copy of the Inquiry report; and (2) notifies the Respondent in writing of the Allegations to be investigated.
- Prior to notifying Respondent of the Allegations, takes all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the proceeding that were not previously sequestered.
- Appoints an Investigation committee and committee chair as soon after the initiation of the Investigation as is practical.
- Prepares a charge for the Investigation committee.
- Convenes the first meeting of the Investigation committee and at that meeting: (1) briefs the committee on the charge, the Inquiry report and the procedures and standards for the conduct of the Investigation, including the need for confidentiality and developing a specific plan for the Investigation; and (2) providing committee members a copy of TCU's policies and procedures and, if the Investigation involves Research Misconduct Allegations, 42 CFR Part 93.
- Provides the Investigation committee with needed any needed support, including expert advice, forensic analysis of evidence, and clerical support.
- Is available throughout the Investigation to advise the committee as needed.
- On behalf of TCU, the RIO is responsible for each of the following steps and for ensuring that the Investigation committee: (1) uses diligent efforts to conduct an Investigation that includes an examination of all research records and evidence relevant to reaching a

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decision on the merits of the Allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (3) interviews each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible Research Integrity Violations, and continues the Investigation to completion.

- Upon determining that the Research Misconduct Investigation cannot be completed within 120 days of its initiation, submits a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.
- Assists the Investigation committee in preparing a draft Investigation report, sends the Respondent a copy of the draft report for his/her comment within 30 days of receipt, takes appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent and ensuring that the comments are included and considered in the final Investigation report.
- Transmits the draft Investigation report to legal counsel for a review of its sufficiency, if necessary.
- Assists the Investigation committee in finalizing the draft Investigation report and receives the final report from the committee.
- Transmits the final Investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receives the report back from the DO for that purpose; or (2) if the DO determines whether or not to accept the report and its findings and recommended actions, transmits to ORI within the time period for completing the Investigation, a copy of the final Investigation report with all attachments, a statement of whether TCU accepts the findings of the report, whether TCU found Research Integrity Violations, and if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.
- When a final decision is reached, the RIO will normally notify both the Respondent and the Complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.
- Maintains and, upon ORI's request, provides to ORI all relevant research records and records of the proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

IV. Research Noncompliance Proceedings

- Research Noncompliance proceedings will be conducted similar to Research Misconduct proceedings, as determined appropriate by the RIO based, in part, on the nature and severity of the allegations or evidence. If the RIO determines that a Research Noncompliance Allegation is a matter that may be handled by a research compliance committee, the RIO will notify the chairperson of such committee of the Allegations and delegate responsibility of the proceeding to the chairperson.
- If a Research Noncompliance Investigation takes place, when a final decision is reached, the RIO will normally notify both the Respondent and the Complainant, if any, in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.