

I. Introduction

These procedures supplement the Research Integrity Policy (“Policy”). All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

II. Rights and Responsibilities

- A. **Research Integrity Officer**. The RIO, or the RIO delegate, has primary responsibility for implementation of TCU policies and procedures on Research Misconduct and Research Noncompliance, and overseeing all related proceedings including:
- Consult confidentially with persons uncertain about whether to submit an Allegation;
 - Receive Allegations;
 - Assess each Allegation to determine if an Inquiry is warranted;
 - As necessary, take interim action and notify ORI (or other regulatory agency) of special circumstances;
 - Sequester Research data and evidence pertinent to the Allegation and maintain it securely;
 - Provide confidentiality to those involved in a proceeding;
 - Notify the Respondent and provide opportunities for the Respondent to review/comment/respond to Allegations, evidence, and committee reports;
 - Inform Respondents, Complainants, and witnesses of the procedural steps of proceeding;
 - If a committee will be used, appoint the chairperson and members of the Inquiry and Investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
 - Determine whether each person, including RIO, involved in handling an Allegation have an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the proceeding (The decisions of the RIO related to conflicts of interest are final);
 - In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith Complainants, witnesses, and committee members and counter potential or actual retaliation against them by Respondents or other institutional members;

- Keep the Deciding Official and others who need to know apprised of the progress of the review of the Allegation;
 - Notify and make reports to ORI and/or other regulatory agencies, as required by applicable law;
 - Ensure that administrative actions taken by TCU and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
 - Maintain records of the proceedings.
- B. Complainant.** The Complainant is responsible for making Allegations in good faith, maintaining confidentiality, and cooperating with the Inquiry and Investigation. The Complainant will be interviewed at the Inquiry and Investigation Stages and given a transcript or recording of the interview for correction.
- C. Respondent.** The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry and Investigation. The Respondent is entitled to:
- A good faith effort from the RIO to notify the Respondent in writing at the time of or before beginning an Inquiry;
 - An opportunity to comment on the Inquiry report and to have comments attached to the report;
 - Be notified of the outcome of the Inquiry, and, if the Allegation involves Research Misconduct, receive a copy of the Inquiry report that includes a copy of, or refers to the PHS Policies on Research Misconduct and the TCU's policies and procedures on Research Misconduct;
 - Be notified in writing of the Allegations to be investigated within 30 days after the RIO decides to investigate, but before the Investigation begins, and be notified in writing of any new Allegations, not addressed in the Inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;
 - Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the Investigation;
 - Have interviewed during the Investigation any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the Investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and

- Receive a copy of the draft Investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by TCU and addressed in the final report.

The Respondent will be given an opportunity to admit that Research Misconduct or Research Noncompliance occurred and that the Respondent committed the Research Misconduct or Research Noncompliance. With the advice of the RIO and/or other institutional officials, the DO may terminate the institution's review of an Allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.

- D. Deciding Official.** The DO will receive and review the Inquiry report and, in consultation with the RIO, and make the final decision regarding if an Investigation is warranted. Any finding that an Investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the Inquiry report within 30 days of the finding. If it is found that an Investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the Inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to investigate.

The DO also will receive and review the Investigation report and, after consulting with the RIO, decide the extent to which TCU accepts the findings of the Investigation. If Research Misconduct or Research Noncompliance is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final Investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI.

III. Conducting the Assessment and Inquiry

- A. Assessment of Allegations.** Upon receiving an Allegation, the RIO will promptly assess the Allegation to determine whether (1) it is sufficiently credible and specific so that potential evidence of Research Misconduct or Research Noncompliance may be identified, and (2) the Allegation falls within the definition of Research Misconduct or Research Noncompliance. An inquiry must be conducted if these criteria are met.

The Assessment period should be brief, preferably concluded within a week. In conducting the Assessment, the RIO need not conduct any interviews, or gather data beyond any that may have been submitted with the Allegation, except as necessary to assess the Allegation. The RIO shall, on or before the date on which the Respondent is notified of the Allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.

- B. Initiation and Purpose of the Inquiry.** If the RIO determines that the criteria for an Inquiry are met, the RIO will immediately initiate the Inquiry process. The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether to

investigate. An Inquiry does not require a full review of all the evidence related to the Allegation.

The RIO, in his/her sole discretion, may decide to combine the Allegation Assessment and Inquiry phase. In such event, the RIO will follow the procedures set forth for an Inquiry.

- C. Notice to Respondent; Sequestration of Research Records.** At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the proceeding, inventory the records and evidence and sequester 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 such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with ORI for advice and assistance.
- D. Appointment of the Inquiry Committee.** The RIO may conduct the Inquiry or, in his/her discretion, choose to appoint an Inquiry committee and committee chairperson. In the event an Inquiry Committee is used, the RIO will appoint the committee as soon after the initiation of the Inquiry as is practical. The Inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Inquiry.
- E. Charge to the Committee and First Meeting.** The RIO will prepare a charge for the Inquiry committee that:
- Sets forth the time for completion of the Inquiry;
 - Describes the Allegations and any related issues identified during the 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 or Research Noncompliance 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 or Research Noncompliance and (2) the Allegation may have substance, based on the committee's review during the Inquiry; and
 - Informs the Inquiry committee that they are responsible for preparing a written

report of the Inquiry that includes the information set forth in Section IV(A) below.

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 available throughout the Inquiry to advise the committee as needed.

- F. Inquiry Process.** The RIO or Inquiry committee (if formed) will normally interview the Complainant, the Respondent, and key witnesses as well as examining relevant research records and materials. Then an evaluation of the evidence, including the testimony obtained during the Inquiry, will take place. A decision will be made as to whether there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct or Research Noncompliance and preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the Allegation may have substance. If the criteria are met, the RIO or Inquiry committee (if formed) will recommend in its Inquiry report that an Investigation is warranted.

While the scope of the Inquiry is not required to decide whether Research Misconduct or Research Noncompliance occurred, if a legally sufficient admission of Research Misconduct or Research Noncompliance is made by the Respondent, a determination may be made at the Inquiry stage if all relevant issues are resolved. In that case, and if appropriate, TCU must promptly consult with ORI to determine the next steps.

- G. Time for Completion.** The Inquiry, including preparation of the final Inquiry report and the decision whether an Investigation is warranted, must be completed within 60 calendar days of initiation of the Inquiry, 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. The RIO will notify the Respondent of the extension.

IV. The Inquiry Report

- A. Elements of the Inquiry Report.** A written Inquiry report must include the following information: (1) The name and position of the Respondent; (2) A description of the Allegations; (3) The PHS support, if any, including, grant numbers, grant applications, contracts, and publications listing PHS support; (4) The basis for recommending that the Allegations warrant an Investigation; and (5) Any comments on the draft report by the Respondent or the Complainant. Modifications should be made as appropriate in consultation with the RIO and the Inquiry committee.

- B. Notification to the Respondent and Opportunity to Comment.** The RIO shall notify the Respondent of the outcome of the Inquiry and include a copy of the draft Inquiry report for comment within 10 days. If the Allegations include Research Misconduct, then the RIO also will provide the Respondent with a copy of, or a reference to, the PHS Policies on Research Misconduct and the TCU's policies and procedures on Research Misconduct. Any comments that are submitted by the Respondent will be attached to the final Inquiry report. Based on the comments, the Inquiry Report may revise the draft report as appropriate and prepare it in final form.

C. Institutional Decision and Notification.

1. Decision by Deciding Official. The RIO will transmit the final inquiry report and any comments to the DO, who, in consultation with the RIO, will determine in writing whether an Investigation is warranted. The inquiry is completed when the DO makes this determination.
2. Notification to ORI, when required. Within 30 calendar days of the decision that an investigation is warranted, the RIO will provide ORI with the written decision and a copy of the Inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.
3. Documentation of Decision Not to Investigate. If the decision is made that an Investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

V. Conducting the Investigation

- A. **Initiation and Purpose.** The investigation must begin within 30 calendar days after the determination by the DO that an Investigation is warranted. The purpose of the Investigation is to develop a factual record by exploring the Allegations in detail and examining the evidence in depth, leading to recommended findings on whether Research Misconduct or Research Noncompliance has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible Research Misconduct or Research Noncompliance that would justify broadening the scope beyond the initial Allegations. This is particularly important where the Allegations involve clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be set forth in an investigation report.
- B. **Notifying ORI and Respondent; Sequestration of Research Records.** On or before the date on which the Investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the Investigation and provide ORI a copy of the Inquiry report (if ORI involvement is required); and (2) notify the Respondent in writing of the Allegations to be investigated. The RIO must also give the Respondent written notice of any new Allegations within a reasonable amount of time of deciding to pursue Allegations not addressed during the Inquiry or in the initial notice of the Investigation.

The RIO will, prior to notifying Respondent of the Allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research

records and evidence needed to conduct Investigation that were not previously sequestered during the Inquiry. The procedures to be followed for sequestration during the Investigation are those that apply during the Inquiry.

- C. Appointment of the Investigation Committee.** If the RIO so chooses, the RIO will appoint an Investigation committee and the committee chair as soon after the beginning of the Investigation as is practical, which may consist of the same individuals appointed to the Inquiry committee, unless any such individual has an unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution.
- D. Charge to the Committee and the First Meeting.** The RIO will prepare a charge for the Investigation committee that:
- Describes the Allegations and related issues identified during the Inquiry;
 - Identifies the Respondent;
 - Informs the committee that it must conduct the Investigation as prescribed in paragraph E. of this section;
 - Defines Research Misconduct or Research Noncompliance, as appropriate;
 - Informs the committee that it must evaluate the evidence and testimony to determine whether Research Misconduct or Research Noncompliance occurred and, if so, the type and extent of it and who was responsible;
 - Informs the committee that to determine that the Respondent committed:
 - Research Misconduct it must find that a preponderance of the evidence (or other standard required by appropriate regulatory agency) establishes that: (1) Research Misconduct occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the Research Misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the Research Misconduct intentionally, knowingly, or recklessly; or
 - Research Noncompliance it must find that the Respondent failed, by action or omission, and intentionally or unintentionally, to applicable law, TCU policies and procedures, or any requirements of or determinations by a research committee; and
 - Informs the committee that it must prepare a written Investigation report that includes all the requirements set forth in Section VI below.

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

Procedures

of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of the Policy and these procedures, and PHS Policies on Research Misconduct. The RIO will be present or available throughout the Investigation to advise the committee as needed. The RIO may include consultants, such legal counsel.

E. Investigation Process. The Investigation committee and the RIO must:

- Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each Allegation;
- Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
- Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible Research Misconduct or Research Noncompliance, and continue the Investigation to completion.

F. Time for Completion. The investigation is to be completed within 120 days of beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI, if required. However, if the RIO determines that the Investigation will not be completed within this 120-day period and ORI involvement is required, the RIO will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VI. The Investigation Report

A. Elements of the Investigation Report. The Investigation committee and the RIO are responsible for preparing a written draft report of the Investigation that:

- Describes the nature of the Allegations, including identification of the respondent;
- Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific Allegations considered in the Investigation;

- Includes the Policy and procedures under which the Investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each Allegation. Each statement of findings will: (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, for Research Misconduct, 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 PHS support or grant agreement proposal; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the Research Misconduct or Research Noncompliance; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

B. Comments on the Draft 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 the Respondent receives the draft report to submit comments to the RIO. The Respondent's comments must be included and considered in the final report.
2. Confidentiality. In distributing the draft report, or portions thereof, to the Respondent, the RIO 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 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 investigation report, including ensuring that the Respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the Investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of Research Misconduct or Research Noncompliance. If this determination varies from the findings of the Investigation committee, the DO will, as part of the 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 a final decision on the case has been reached, the RIO will normally notify both the Respondent and the Complainant in writing. After informing ORI (if necessary), the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have

Procedures

been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

- D. Notice to ORI of Institutional Findings and Actions.** When required, unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to ORI: (1) a copy of the final Investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the Investigation report; (3) a statement of whether the institution found Research Misconduct and, if so, who committed the Research Misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.
- E. Maintaining Records for Review by ORI.** The RIO must maintain and provide to ORI upon request “records of Research Misconduct proceedings”. Unless custody has been transferred to HHS 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 PHS proceeding involving the Allegation. The RIO is responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an Allegation or of the institution’s handling of such an Allegation.

VII. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. When required, the RIO will notify ORI in advance if there are plans to close a case at the Inquiry or Investigation 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 as required.

VIII. Institutional Administrative Actions

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

- 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 or Research Noncompliance.

IX. Other Considerations

- A. Termination 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 has been reported, will not preclude or terminate the proceeding or otherwise limit any of the institution's responsibilities.

If the Respondent, without admitting to the Research Misconduct or Research Noncompliance, elects to resign his or her position after the institution receives an Allegation, 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. Protecting the Respondent.** During the proceeding, the Respondent may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case, provided, however, that any such attorney or advisor's presence is restricted to the role of advising the Respondent (as opposed to representing).

Following a final finding of no Research Misconduct or Research Noncompliance, including ORI concurrence where required, the RIO must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the circumstances and the views of the Respondent, the RIO should consider notifying those individuals aware of or involved in the Investigation of the outcome, publicizing the outcome in any forum in which the Allegation was previously publicized, and expunging all reference to the 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 proceeding and upon its completion, regardless of the institution or ORI final determination, the RIO will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made Allegations in good faith and of any witnesses and committee members who cooperate in good faith with the 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 implementing any steps the DO approves.

- D. Allegations Not Made in Good Faith.** If necessary, the DO will determine whether the Complainant's Allegations 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 the DO will determine whether any administrative action should be taken against the person who failed to act in good faith.