

The University of North Texas Health Science Center (HSC)**Research Integrity Procedural Manual****Standard Operating Procedures**

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I. Introduction

The University of North Texas Health Science Center (HSC) Research Integrity Policy (8.106) describes the university's commitment to maintaining the integrity of the research process. Because incidents of research misconduct compromise the integrity of the research process, allegations of research misconduct must be processed appropriately. The HSC Research Integrity Procedural Manual describes the principles and the procedures for responding to allegations of research misconduct in an effective, fair, and timely manner.

Note that all Public Health Service (PHS) supported/funded research must adhere to the federal regulations for Research Misconduct, at [42 CFR Part 93 \(PHS Policies on Research Misconduct\)](#).

Additional information and guidance regarding the federal research misconduct policy can be found on the HHS Office of Research Integrity (ORI) website: <https://ori.hhs.gov/federal-research-misconduct-policy>

II. Definitions

The HSC Research Integrity Policy (8.106) defines the words and phrases associated with research integrity issues. The same definitions shall be used in this procedural manual as those used in the research integrity policy.

III. Consultation about Concerns of Research Misconduct

The Vice President for Research (or his/her designated staff member from the Division of Research and Innovation) is responsible for consulting with persons uncertain about whether to submit an allegation of research misconduct. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the Vice President for Research to discuss the suspected research misconduct.

Note that for PHS supported/funded research, or for any general questions regarding reporting of or procedures for managing a research integrity case / research misconduct allegation, the Vice President for Research or designee should contact the HHS Office of Research Integrity (<https://ori.hhs.gov/>), Division of Investigative Oversight, to discuss the incident and seek appropriate guidance.

IV. Preliminary Assessments of Allegations of Research Misconduct

The assessment period should be brief, preferably concluded within ten (10) business days.

In conducting the assessment, the Vice President for Research need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If the circumstances described by the Complainant do not meet the definition of research misconduct, the Vice President for Research will refer the Complainant or allegation to other offices or officials with responsibility for resolving the problem.

V. The Committee for Research Integrity (CRI)

A. Purpose

Following the assessment of an allegation, a Committee for Research Integrity shall be formed to conduct all inquiries and investigations relating to research misconduct involving HSC personnel.

B. Composition

The Committee must consist of at least five (5) individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the

allegation of research misconduct 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, conduct the inquiry and investigation as needed.

C. Appointment of Members

The Vice President for Research shall appoint members of the Committee for Research Integrity and ensure the Committee is properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence.

D. Appointment of the Chair

The Vice President for Research shall appoint the chair of the Committee (the Vice President for Research or RIO may serve as chair).

If the Vice President for Research is the subject of a research misconduct/integrity inquiry, the Provost and Executive Vice President of Academic Affairs shall serve as the Chair of the Committee for Research Integrity.

E. Length of Term/Service

Excepting the Vice President for Research or designee, who shall be a permanent member of the Committee, each member will serve a term as needed. In the event that the Committee becomes a “standing committee”, appointments shall be for a three-year appointment.

Except for the initial Committee, in the event of a standing Committee, members will be appointed on a staggered basis each year from among qualified persons by the Vice President for Research.

F. Member Removal

Any member of the Committee for Research Integrity may be excused from the Committee and its deliberations by the Vice President for Research for any reason at any time.

VI. The Inquiry

A. Preparing for the Inquiry

1. Notice to Respondent

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.

2. Establishing the Committee's Membership

The Vice President for Research shall appoint members of the Committee for Research Integrity (CRI) as described in this manual.

The RIO shall notify the Respondent of the proposed committee membership. The Respondent shall have ten (10) business days to submit an objection and provide a relevant justification to object to the involvement of a proposed member based upon a personal, professional, or financial conflict of interest. The Vice President for Research will review any such objections and justifications and make a final determination as to whether a conflict of interest exists and appoint substitute committee members as needed.

3. Developing a Charge to the Committee for the Inquiry

The Vice President for Research will prepare a charge for the Committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegation and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines:
 - (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and,
 - (2) the allegation may have substance, based on the Committee's review during the inquiry;
- Informs the Committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this procedural manual as well as the HHS ORI (see the [ORI Outline for Inquiry-Investigation Reports](#)).

B. The Committee's Review of the Inquiry

An inquiry does not require a full review of all the evidence related to the allegation.

The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if an

admission of research misconduct is made by the Respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved.

Note: Concerning the admission itself, a verbal admission does not meet ORI/federal requirements to establish culpability. The Respondent should provide a detailed written admission to the institution with the following content:

- *Identify affected data with specifics (e.g., what publication(s), grant application(s), and/or research record was falsified and fabricated).*
- *Be specific and do not generalize (e.g., type of data manipulations; fabrication, falsification, plagiarism). The misconduct admissions should be limited to the affected data only.*
- *Include the full scope of the misconduct.*

The admission should not:

- *Contain any language admitting to “errors” instead of falsification, fabrication, or plagiarism.*
- *Claim lack of knowledge, training, instrument failure, and/or personal circumstances. The committee may document and include extenuating circumstances in the draft report, but the written admission should only focus on what misconduct occurred.*
- *Fail to disclose exactly where the affected data were used, reported, or recorded.*
- *Fail to consider data used in PHS (e.g., NIH) grant applications.*

The Respondent should sign and date the final admission document.

A hypothetical example of an adequate written admission may include such bulleted statements as:

“I committed research misconduct by falsifying Figure 3B of NIGMS/NIH grant R01 XXXXX by reusing and relabeling western blot data representing hypothetical cancer cell line treated with hypothetical drug in Figure 1C of Hypothetical Journal 2020.”

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

At the Committee's first meeting, a representative of the UNT System Office of General Counsel will advise the Committee on confidentiality and other legal issues pertinent to the inquiry. The Office of General Counsel should be consulted throughout the inquiry on

compliance with the research integrity policy (8.106) and this manual and applicable state and federal regulations on research misconduct.

The RIO is responsible for informing Respondents, Complainants, witnesses, and members of the Committee for Research Integrity of the procedural steps in the research misconduct proceeding, the need for confidentiality, and providing procedural guidance throughout the proceeding. The RIO is also responsible for notifying the Respondent and providing the Respondent with opportunities to review/comment/respond to the allegation, evidence, and committee reports in accordance with this procedural manual, federal regulations, and applicable regulations of any involved funding entity.

Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice but may not bring the counsel or personal adviser to Committee interviews or meetings on the case. The Respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct.

The Complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The Committee will normally interview the Complainant, the Respondent and key witnesses as well as examine relevant research records and materials. Then the Committee will evaluate the evidence, including the testimony obtained during the inquiry.

After consultation with the RIO, the Committee members will make a recommendation as to whether an investigation is warranted based on the criteria in the Research Integrity Policy (8.106), this manual, and in accordance with federal regulations.

C. The Inquiry Report

1. The Inquiry Report: Elements

A written inquiry report must be prepared that includes the following information (as available and applicable): (1) the name and position of the Respondent; (2) a description of the allegation of research misconduct; (3) funding support, including, for example, grant numbers, grant applications, contracts and publications listing funding support; (4) the basis for recommending or not recommending that the allegation warrants an investigation; (5) any comments on the draft report by the Respondent or Complainant; (6) a list of the research records reviewed; (7) summaries of any interviews; and (8) whether any other actions should be taken if an investigation is not recommended.

See also the [ORI Outline for Inquiry-Investigation Reports](#), for guidance on preparing the Inquiry Report.

2. Inquiry Report: Draft (Notices and Comments)

a. Notice to the Deciding Official and the Research Integrity Officer

Any recommendation that an investigation is warranted must be made in writing by the Committee, to the Provost & Executive Vice President for Academic Affairs, as described in this manual. A copy of this recommendation shall be provided to the RIO and the Vice President for Research.

b. Notice to Respondent

The RIO shall notify the Respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within ten (10) business days, and include a copy of UNTHSC's policy (8.106) and procedures on research integrity. The Respondent is entitled to an opportunity to comment on the inquiry report within ten (10) business days and have his/her comments attached to the report.

c. Notice to the Office of General Counsel

The Office of General Counsel should review the report for legal sufficiency.

3. The Inquiry Report: Final Version

Modifications should be made as appropriate in consultation with the RIO and the Committee for Research Integrity. Any comments that are submitted will be attached to the final inquiry report. Based on the comments, the Committee may revise the draft report as appropriate and prepare it in final form.

D. The Final Determination by the Deciding Official/Results of the Inquiry

The Vice President for Research will transmit the final inquiry report and any comments to the Provost & Executive Vice President for Academic Affairs (the Deciding Official), who will determine in writing whether an investigation is warranted. The Provost & Executive Vice President for Academic Affairs will receive the inquiry report and after consulting with the Vice President for Research, decide whether an investigation is warranted under the Research Integrity Policy (8.106). The inquiry is completed when the Provost & Executive Vice President for Academic Affairs makes this determination.

E. Notices of the Results of the Inquiry

Any finding that an investigation is warranted must be made in writing by the Provost & Executive Vice President for Academic Affairs, as described in this manual.

1. Notice to the Respondent

On or before the date on which the investigation begins, the RIO must notify the Respondent in writing of the allegation to be investigated. The RIO must also give the

Respondent written notice of any new allegation of research misconduct within a reasonable amount of time of deciding to pursue an allegation not addressed during the inquiry or in the initial notice of the investigation.

2. Notice to HSC Officials

The Vice President for Research will notify the relevant HSC officials of the Provost & Executive Vice President for Academic Affairs' decision.

3. Notice to ORI

Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report. Upon request of ORI, the submission should also include: (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 for the investigation to consider.

F. Time Limit for Completing the Inquiry; Extension of Time Limit

The inquiry, including preparation of the final inquiry report and the decision of the Provost & Executive Vice President on Academic Affairs on whether an investigation is warranted, must be completed within sixty (60) business days of initiation of the inquiry, unless the Vice President for Research determines that circumstances clearly warrant a longer period. If the Vice President for Research approves an extension, the inquiry record must include documentation of the reasons for extending the inquiry period.

G. Documentation of Decision Not to Investigate

If the appropriate HSC institutional officials (DO, Vice President for Research) determine that an investigation will not be conducted, sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation must be kept (consistent with 93.317, institutions must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel).

VII. The Investigation

A. Preparing for the Investigation

1. Developing a Charge to the Committee for the Investigation

The RIO will define the subject matter of the investigation in a written charge to the Committee for Research Integrity that:

- Describes the allegation and related issues identified during the inquiry;
- Identifies the Respondent(s);
- Informs the Committee that it must conduct the investigation as prescribed in the Research Integrity Policy (8.106), this manual, and federal regulations;
- Defines research misconduct;
- Informs the Committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the Committee that in order to determine that the Respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in the policy (8.106), 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; and
- Informs the Committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of the policy (8.106), federal regulations, and the applicable regulations of any involved funding entity.

B. The Committee's Review of the Investigation

The RIO will convene the first meeting of the 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 and for developing a specific investigation plan. The Vice President for Research will be present or available throughout the investigation to advise the committee as needed.

The Committee will be provided with a copy of the policy (8.106) and procedures and the applicable regulations and/or requirements of any involved funding entity.

The 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, and continue the investigation to completion.

The Complainant must be interviewed during an investigation.

The Respondent is entitled to 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. The Respondent is also entitled to have interviewed during the investigation any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the investigation.

C. The Investigation Report

1. The Investigation Report: Elements

The Committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the Respondent. The Respondent's curriculum vitae or resume may be included as part of the identification.
- Describes and documents any funding entity support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing any funding support;
- Describes the specific allegation of research misconduct considered in the investigation;

- Includes the UNTHSC policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to the relevant office of any involved funding entity previously;
- 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 of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify any funding entity support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the Respondent has pending with other funding entities.

See also the [ORI Outline for Inquiry-Investigation Reports](#), for guidance on preparing the Investigation Report.

2. The Investigation Report: Draft (Notices and Comments)

a. Notice to the Respondent

The RIO must give the Respondent a copy of the draft investigation report for comment. The Respondent will be notified that any comments must be submitted to the Vice President for Research within thirty (30) days from the date he/she received the draft report. The Respondent will be notified that the provided written comments will be included in the final report.

b. Notice to the Office of General Counsel

The draft investigation report will be transmitted to the Office of General Counsel for a review of legal sufficiency, and their comments, if any, should be incorporated into the report as appropriate.

3. The Investigation Report: Final Version

The RIO will assist the Committee in finalizing the draft investigation report, ensuring that the Respondent's (and Complainant's) comments are included and will

transmit the final investigation report to the Vice President for Research and the Provost & Executive Vice President for Academic Affairs.

D. Results of The Investigation

1. The Determination by the Deciding Official

The Provost & Executive Vice President for Academic Affairs (the Deciding Official) will determine in writing: (1) whether HSC accepts the investigation report, its findings, and the recommended actions; and (2) the appropriate HSC action(s) in response to the accepted findings of research misconduct and will convey that determination to the Vice President for Research.

If this determination varies from the findings of the investigation committee, the Provost & Executive Vice President for Academic Affairs will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the Provost & Executive Vice President for Academic Affairs may return the report to the Vice President for Research and the investigation committee with a request for further fact-finding or analysis.

2. Notice to ORI of Institutional Findings and Actions

The institution must give ORI the following:

(a) **Investigation Report.** Include a copy of the report, all attachments, and any appeals.

(b) **Final institutional action.** State whether the institution found research misconduct, and if so, who committed the misconduct.

(c) **Findings.** State whether the institution accepts the investigation's findings.

(d) **Institutional administrative actions.** Describe any pending or completed administrative actions against the respondent.

E. Notices of the Results of the Investigation

1. Notice to the Committee for Research Integrity, Respondent, and Complainant

When a final decision on the case has been reached by ORI, the Vice President for Research will normally notify the Committee for Research Integrity, the Respondent, and the Complainant in writing. Notice shall also be given to HSC compliance committees, as appropriate.

2. Notice to Funding Entity

Unless an extension has been granted, the Vice President for Research must, within the one hundred twenty (120) business days (the period for completing the investigation), submit information (described elsewhere in this manual) to the relevant office of an involved funding entity if required by state or federal regulation.

The Provost & Executive Vice President for Academic Affairs shall submit this information to the relevant office of an involved funding entity.

3. Notice to Other Relevant Parties

After informing the relevant office of any involved funding entity if there is a federal or state requirement to do so, the Provost & Executive Vice President for Academic Affairs 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.

F. Time Limit for Completing the Investigation; Extension of Time Limit

The investigation is expected to be completed within one hundred twenty (120) business 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 the relevant office of any involved funding entity. However, the Vice President for Research may extend the time period for completion of the investigation.

VIII. Requirements for Reporting to the Funding Entity

A. Individual Responsible for Reporting to the Funding Entity

The Vice President for Research is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The Vice President for Research is responsible for notifying and making reports to the relevant office of an involved funding entity in accordance with federal or state requirements.

B. Reporting Health or Safety Concerns to the Funding Entity

The Vice President for Research shall, at any time during a research misconduct proceeding, immediately notify the relevant office of an involved funding entity in accordance with federal or state notification requirements or as he/she deems necessary to meet a health or safety concern, if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- Funding entity resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal or state action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and funding entity action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

C. Providing Items Requested by the Funding Entity to the Funding Entity

The Vice President for Research is responsible for providing any information, documentation, research records, evidence or clarification requested by the funding entity to carry out its review of an allegation of research misconduct or of the handling of such an allegation by UNTHSC.

D. Providing Records of Research Misconduct Proceedings to the Funding Entity

The Vice President for Research must maintain and in accordance with state or federal regulation, provide to the relevant office of any involved funding entity upon request “records of research misconduct proceedings” as that term is defined by the applicable regulation of any involved funding entity.