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Misconduct in Research and Other Scholarly Activity

Scope

All University of Texas Health Science Center at Tyler (the "University") staff involved in research

Purpose

To define expectations and consequences for misconduct in research and other scholarly activity.

Definitions

- A. **Allegation** means any written or oral statement or other communication of possible misconduct in research or other scholarly activity made to a University or HHS official.
- B. **Complainant** means a person who in good faith makes an allegation of misconduct.
- C. **Conflict of Interest** means the real or apparent interference of one person's interests with the interests of another person or entity, where the potential bias may occur due to prior or existing personal or professional relationships.
- D. **Deciding Official** means the University official who makes final determination on allegations of misconduct and any responsive University administrative actions. The President of the University is the Deciding Official.
- E. **Evidence** means any document, tangible item, or testimony offered or obtained during a misconduct proceeding that tends to prove or disprove the existence of an alleged fact.
- F. **Good Faith Allegation** means an allegation made with the honest belief that misconduct may have occurred. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- G. **HHS** means the United States Department of Health and Human Services.
- H. **Inquiry** means preliminary information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
- I. **University member** means a person who is employed by, is an agent of, or is affiliated by contract or agreement with the University. University 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 fellow, students, volunteers, agents, and contractors, subcontractors, and sub-awardees, and their employees.

- J. **Investigation** means the formal development of a factual record and examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct which may include a recommendation for other appropriate actions, including administrative actions.
- K. **Investigation Committee** means a committee appointed by the Research Integrity Officer to explore in detail the allegations, to examine evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent.
- L. **Misconduct** in research or other scholarly activity includes fabrication, falsification, plagiarism or other practices that seriously deviate from ethical standards for proposing, conducting, or reporting research or other scholarly activity:
 - 1. Fabrication is making up data or results and recording or reporting them.
 - 2. Falsification is manipulating research or scholarly materials, equipment, or processes, or changing or omitting data or results such that the research or scholarship is not accurately represented in the record.
 - 3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Misconduct in research or other scholarly activity does not include honest error or differences of opinion.

- M. **ORI** means the Office of Research Integrity in HHS. ORI is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Services (PHS).
- N. **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.
- O. **PHS or Public Health Service** means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Services, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.
- P. **PHS support** means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training or activities related to that research or training that may be provided through: PHS grants, cooperative agreements, or contracts or sub-grants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.
- Q. **Research Integrity Committee** means a group of University officials appointed by the President to determine and review research integrity policy. Based on the Research Integrity Officer's preliminary assessment, the Research Integrity Committee will determine if an inquiry is necessary.
- R. **Research Integrity Officer** means the University official responsible for overseeing the inquiry and investigation into allegations of misconduct in research or other scholarly activity. The RIO will serve as the Chair of the Research Integrity Committee.
- S. **Research Record** means the record of data or results that embody 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 HHS or a University official by a respondent in the course of the misconduct proceeding.

T. **Respondent** means the person or persons against whom an allegation of misconduct is directed or who is subject of a misconduct proceeding. There can be more than one respondent in any inquiry or investigation.

U. **Retaliation** means an adverse action taken against a complainant, witness, or committee member by this University or one of its members in response to (1) a good faith allegation of misconduct; or (2) good faith cooperation with a misconduct proceeding.

POLICY

A. General Policy

The University is committed to promoting a research community whose members faithfully adhere to high ethical standards of honesty and integrity. Misconduct in scholarly activity, as defined in this policy and in applicable federal and state laws and regulations, will not be tolerated and may subject offenders to discipline up to and including termination of employment. The University seeks to adhere to this policy without inhibiting the productivity and creativity of that community. The University expects faculty and other research personnel to avoid misconduct in science and other scholarly research. Misconduct violates not only the relationship between a researcher and the University but also damages the reputations of those involved and of the entire research and scholarly community. Therefore, it is the responsibility of every research investigator to avoid misconduct and to assure integrity in the collection of data, storage of records and proper assignment of credit in publication. It is also the responsibility of all researchers and scholars to report instances of misconduct, as well as instances of retaliation against those who, in good faith, bring charges of misconduct in research.

B. Scope and Application

1. This policy is intended to carry out the University's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This policy applies to any person paid by, under the control of, or affiliated with the University, by contract or agreement, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, contractors of the University, or collaborators at the University.
2. The policy and its procedures will be followed when a University official receives an allegation of possible misconduct in research or other scholarly activity (including fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). Particular circumstances in an individual case may dictate variation from the normal procedure if deemed in the best interest of the University and research sponsor. Change from normal procedures must ensure fair treatment to the subject of the allegation. Any significant variation should be approved in advance by the University's Research Integrity Committee.

Procedures

A. Responsibility to Report Misconduct

1. All employees or individuals associated with the University should report observed, suspected, or apparent misconduct in research or other scholarly activity to the Research Integrity Officer or Vice Chair of the Research Integrity Committee. Any official who receives an allegation of misconduct

must report it immediately to the Research Integrity Officer.

2. If any individual is unsure whether a suspected incident falls within the definition of misconduct in research or other scholarly activity, he or she may meet with or contact the Research Integrity Officer on an informal, anonymous and/or hypothetical basis and will be referred to other offices or officials if the circumstances do not meet the definition of misconduct.
3. At any time, an employee may have confidential discussions about concerns of possible misconduct with the Research Integrity Officer or Vice Chair of the Research Integrity Committee and will be counseled about appropriate procedures for reporting allegations.

B. Confidentiality

The Research Integrity Officer shall, as required: (1) limit disclosure of the identify of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a misconduct proceeding. The Research Integrity Officer should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

C. Protecting Complainants, Witnesses, and committee Members

1. The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct and of those who cooperate in inquiries or investigations to ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the University.
2. The University will, to the maximum extent possible, protect the privacy of those who make good faith reports of misconduct. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.
3. In the event of an investigation, the complainant will have the opportunity to testify before the investigation committee; review portions of the investigation report pertinent to his or her allegations or testimony; be informed of the results of the investigation; and be protected from retaliation. The complainant will be given pertinent portions of draft reports for comment if the Research Integrity Officer determines that he or she may be able to provide relevant information on those portions of the draft.
4. The complainant is responsible for making allegations in good faith, maintaining confidentiality; and cooperating fully with any inquiry or investigation. Individuals who make frivolous allegations or bring them in bad faith shall be subject to disciplinary action.
5. Witnesses will be afforded similar protections as respondents and complainants with regard to privacy and protection from retaliation. Witnesses are responsible for making allegations in good faith, maintaining confidentiality; and cooperating fully with any inquiry or investigation. Witnesses may receive a transcript or summary of their interviews for review, correction of errors, addition of information or comments. Interviews with witnesses will be recorded or summarized. Changes to a transcript or summary will be made only to correct factual errors.

D. Protecting the Respondent

1. The University is required to make a good faith effort, at the time of or before commencing an inquiry, to inform the respondent of the allegations and to notify the respondent in writing of the conclusion of

the Research Integrity Committee.

2. The University will ensure fair treatment of the respondent and confidentiality to the extent possible without compromising public health and safety or the ability to thoroughly conduct an inquiry or investigation. No person involved in resolving an allegation of misconduct shall have real or apparent conflicts of interest in the matter.
3. The respondent will have the opportunity to: (1) be interviewed as a part of the initial inquiry; (2) to present evidence to the investigation committee; (3) review the draft inquiry and investigation reports; and (4) be informed of the results of the inquiry and the investigation.
4. The respondent may employ outside counsel at his or her expense at any stage of the proceedings described in this policy. Counsel may accompany the respondent in meetings but may not ask questions or offer testimony. The role of counsel is limited to that of advisor to the respondent.
5. The respondent is responsible for maintaining confidentiality and cooperating with the inquiry or investigation.
6. The respondent has the right to receive University assistance in restoring his or her reputation if found not to have engaged in misconduct.

E. Cooperation with Inquiries and Investigations

University members will cooperate with the Research Integrity Officer, Committee, and other University officials in the review of allegations and the conduct of inquiries and investigations. University members, including respondents, have an obligation to provide evidence relevant to misconduct allegations to the Research Integrity Officer or other University officials.

F. Interim Administrative Actions and Notifying ORI of Special circumstances

Throughout the misconduct proceeding, the Research Integrity Officer will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported or other research process. In the event of a threat to PHS supported research, the Research integrity Officer will, in consultation with other University officials and ORI, take appropriate interim action to protect against any such threat.

Immediate notification will be provided to ORI if any of the following conditions exist in PHS supported research:

1. Health or safety of the public is at risk, including an immediate need to protect human (e.g. a clinical trial) or animal subjects;
2. HHS resources or interests are threatened;
3. Research activities should be suspended;
4. There is a reasonable indication of possible violations of civil or criminal law;
5. Federal action is required to protect the interests of those involved in the misconduct proceeding;
6. The misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
7. The research community or public should be informed.

G. Notifying NIH

NIH will be notified to assess the impact of research misconduct on the continuation of the research project as originally approved by NIH. If the institution determines that a change of scope or a change of PD/PI or other senior/key personnel is required, approval from NIH will be sought (NOT-OD-19-020).

H. Preliminary Assessment of Allegations

1. Upon receiving an allegation of misconduct in research or other scholarly activity, the Research Integrity Officer will immediately inform the complainant of University policy and procedures and will bring the allegation to the Research Integrity Committee. The Research Integrity Committee will then assess the allegation to determine whether there is a sufficiently credible and specific allegation that if proved would meet the definition of misconduct.
2. The assessment period should be brief. In conducting the assessment, the Research Integrity Officer 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 to warrant an inquiry.
3. The Research Integrity Officer may, at or before the time which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the misconduct proceeding. The University must take all reasonable and practical steps to obtain custody and sequester all research records and evidence needed to conduct the misconduct proceeding. Where 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. Research records, including those produced under PHS grants and cooperative agreements, are the property of the University, and employees cannot interfere with the University's right to them. Under contracts, records may belong to PHS or other funding sources, but the University will be granted access to them. Research records may be sequestered from other individuals such as co-authors, collaborators or complainants. A dated receipt identifying the sequestered items should be prepared and a copy given to the person from whom the items were collected. Copies of the sequestered items shall be supplied as soon as feasible if requested by the person from whom they were collected. Access to originals must be under direct and continuous supervision of a University official. Sequestered records and materials should be locked in a secure place. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified.
4. Prior to notifying the Complainant of a final decision, the Research Integrity Committee will inform the Senior Vice President of Research of their decision. The Research integrity Committee will then notify the Complainant, in writing, if the Research Integrity Committee determines that an allegation does not warrant an inquiry.

I. Evidentiary Standards

1. The evidentiary standard of proof for misconduct proceedings shall be as follows: A University or Health and Human Services (HHS) finding of misconduct must be proved by a preponderance of the evidence.
2. The University or HHS has the burden of proof for making a finding of misconduct in research or other scholarly activity. The destruction, absence of, or respondent's failure to provide research or other records adequately documenting questioned research or other scholarly activity is evidence of misconduct where the University or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had records and destroyed them, had the opportunity to maintain the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research or scholarship community.
3. The respondent has the burden of going forward with and the burden of proving, by a preponderance

of the evidence, any and all affirmative defenses raised. In determining whether HHS or the University has carried the burden of proof imposed by this section, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

4. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a misconduct proceeding.

Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

1. The Research Integrity Committee will initiate an inquiry immediately upon receipt of allegations of misconduct that warrant an inquiry and will advise the Senior Vice President of Research that an inquiry is being initiated. The Research Integrity Officer will clearly identify the original allegations and any related issues that should be evaluated during the inquiry process.
2. The purposes of the inquiry are: (1) to determine if the allegations fall within the scope of this policy; (2) to determine if the allegations are sufficiently specific to allow follow up; (3) to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and essential witnesses; and (4) to determine whether there is sufficient evidence of possible misconduct in research or other scholarly activity to warrant an investigation.
3. An inquiry does not require a full review of all the evidence related to the allegation.

B. Notice to Respondent; Sequestration of the Research Records

1. At the time of or before beginning an inquiry, the Research Integrity Officer 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. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the Research Integrity Officer must take all reasonable and practical steps to obtain custody of all the records and evidence needed to conduct the misconduct proceeding, inventory the records and evidence and sequester them in a secure manner.

C. Advice

The Senior Vice President for Research, University counsel, UT System Office of General Counsel or any legal counsel that may have been arranged will be available throughout the inquiry to advise the Research Integrity Officer, Research Integrity Committee and/or Senior Vice President for Research and should be consulted as needed at all stages when dealing with allegations of misconduct.

D. The Inquiry Committee

1. The Research Integrity Committee will conduct the inquiry into the allegations. The Research Integrity Committee will have the authority to appoint experts as necessary to evaluate specific allegations.
2. Within ten (10) days of deciding to initiate an inquiry, the Research Integrity Committee will notify ORI and the respondent of the pending inquiry. If the respondent submits a written objection to any member of the Research Integrity Committee or expert based on bias or conflict of interest within five (5) days of receiving notice that an inquiry has been initiated, the Research Integrity Committee will determine whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the Research Integrity Committee that describes the allegations and sets forth the time for completion of the inquiry. The purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible misconduct to warrant an investigation. The purpose is **not** to determine whether misconduct definitely occurred or who was responsible. The Research Integrity Officer must also inform the committee members that they are responsible for preparation of a written report of the inquiry.

F. Inquiry Process

The Research Integrity Committee will normally interview the complainant, the respondent, and key witnesses as well as examine relevant records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. The committee members will decide whether there is sufficient evidence of possible misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, with PHS supported research, the University shall promptly consult with ORI to determine the next steps that should be taken.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the President on whether an investigation is warranted, must be completed within sixty (60) calendar days of initiation of the inquiry, unless the Research Integrity Officer determines that circumstances clearly warrant a longer period. If the Research integrity Officer approves an extension, the inquiry records must include documentation of the reasons for exceeding the sixty (60) day period. The respondent must be notified of the extension.

The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the respondent, Research Integrity Committee members and experts, if any; (1) the allegations; (2) a summary of the inquiry process used; (3) a list of the research records reviewed; (4) summaries of any interviews; (5) a description of the evidence; (6) any PHS support including grant numbers; (7) publications listing any PHS support; (8) any comments on the report by the respondent or the complainant; and (9) the Research Integrity Committee's determination as to whether an investigation is recommended.

B. Comments on the Draft Report by the Respondent and the Complainant

1. The Research Integrity Officer will notify the respondent whether the inquiry found an investigation to be warranted, provide the respondent with a copy of the draft inquiry report for comment and rebuttal and shall include a copy of or refer to 42 CFR Part 93, for PHS supported research, and the University's policies and procedures on misconduct in research or other scholarly activity. The University shall notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment. A confidentiality agreement is a condition for access to the report.
2. Within ten (10) calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or 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 the report as appropriate.

C. Inquiry Decision and Notification

1. The Research Integrity Committee will transmit the final report and any comments to the President, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible misconduct to justify conducting an investigation. The inquiry is completed when the President makes this determination.
2. For PHS supported research, within thirty (30) calendar days of the President's decision that an investigation is warranted, the Research Integrity Officer will provide ORI with the President's written decision and a copy of the inquiry report. The Research Integrity Officer will provide the following to ORI upon request: (1) the University policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings or any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.
3. The Research Integrity Officer will notify both the respondent and the complainant in writing of the President's decision of whether to proceed to an investigation.
4. If the President decides that an investigation is not warranted, the Research Integrity Officer shall secure and maintain for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI for PHS supported research of the reasons why an investigation was not conducted. For PHS supported research, these documents must be provided to ORI or other authorized HHS personnel upon request.

Conducting the Investigation

A. Initiation and Purpose of the Investigation

The investigation must begin within thirty (30) calendar days after the determination by the President that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring 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 additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. The findings of the investigation will be set forth in an investigation report.

B. Institutional Responsibilities

Necessary steps will be taken to protect the scientific integrity of the project, protect human participants, live vertebrate animals and the environment. Steps will be taken to ensure proper expenditure of funds and, if appropriate, continuation of the project during the investigation. ORI and NIH will be notified of the steps taken (NOT-OD-19-020).

C. Notifying ORI and Respondent; Sequestration of the Research Records

On or before the date on which the investigation begins, the Research Integrity Officer must: (1) if the research is supported by PHS, notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. This notification should include a copy of the inquiry report, specific allegations, any PHS funding involved, a copy of the misconduct policy, right to be interviewed with or without counsel, to comment on the draft investigation report, notification that ORI will perform an oversight review of the report if PHS support is involved, and an explanation of the respondent's right to request a hearing if PHS support is involved before the HHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition. The Research Integrity Committee will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. 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. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

D. Appointment of the Investigation Committee

1. The Research Integrity Officer, in consultation with the Senior Vice President for Research and the appropriate department head will appoint an Investigation Committee within ten (10) days after the notification to the respondent that an investigation is planned, or as soon thereafter as is practicable. Such committees will be composed of three (3) persons, including a committee chair. At least one (1) University faculty member shall be appointed to each such committee. No committee members shall have real or apparent conflicts of interest in the case. Committee members shall be unbiased and have the necessary expertise to effectively interview the principals and other witnesses and to evaluate the evidence and issues related to the allegations. Committee members may be scientists, subject matter experts, administrators, lawyers, or other qualified persons within or outside the University. Members of the Investigation Committee may also have assisted in the earlier inquiry concerning the allegations.
2. The Research Integrity Committee will notify the respondent of the proposed Investigative Committee membership. If the respondent submits a written objection to any appointed member of the Investigative Committee based upon bias or conflict of interest within five (5) days, the Research Integrity Committee will determine whether to replace the challenged member with a qualified substitute.
3. The Research Integrity Officer will prepare a charge for the Investigation Committee that describes the allegations and any related issues identified during the inquiry, defines misconduct, and identifies the name of the respondent. The charge will state that the Investigation Committee is to (1) evaluate the evidence and testimony of the respondent, complainant, and witnesses to determine whether, based upon a preponderance of the evidence, (2) misconduct occurred and, if so, the type, and to what extent, (3) the misconduct is a significant departure from accepted practices of the relevant community (4) the respondent committed the misconduct intentionally, knowingly, or recklessly; and (5) who was responsible.
4. If during the investigation additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the Investigation Committee will notify the Research Integrity Committee, which will then determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.
5. The Research Integrity Officer, with the assistance of the Senior Vice President for Research, 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 and for developing a specific investigation plan. The Investigation Committee will be provided with a copy of these instructions and, where PHS funding is involved, a copy of 42 CFR Part 93.

E. Investigation Process

The Investigation Committee will be appointed and the process initiated within thirty (30) days after the completion of the inquiry. 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. The committee, when possible, should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. The committee shall take reasonable steps to

ensure an impartial and unbiased investigation to the maximum extent practical. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file. The committee shall pursue all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible misconduct, and continue the investigation to completion. An investigation normally should 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 findings; making the draft report available to the respondent for comment; and submitting the report to the President for final action.

The Investigation Report

A. Elements of the Investigation Report

The Investigation committee shall prepare a written draft report of its investigation for submission to the President. The report shall describe the nature of the allegation of misconduct including identification of the respondent, a description of any PHS support including any grants, grant applications, contracts, and publications listing such PHS support, specific allegations of misconduct, the policies and procedures under which the investigation was conducted, how and from whom information relevant to the investigation was obtained, the findings of each allegation, and the basis for the findings. It shall also contain an accurate summary of the views of any person(s) found to have engaged in misconduct.

The report shall include a statement of findings for each allegation of misconduct. Each statement of findings must: (1) identify whether the 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/she did not engage in misconduct because of an honest error or a difference of opinion; (3) identify any specific PHS 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 non-PHS federal agencies.

B. Comments on the Draft Report

The Research Integrity Committee will provide the respondent with a copy of the report for comment and rebuttal; and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed thirty (30) days from the date he/she received the draft report to submit comments to the Research integrity Committee. The complainant may, as decided on a case-by-case basis by the Investigation committee, also receive a copy of the report, or relevant portions of it, for comment. The Research Integrity Committee will inform the respondent and complainant, when providing them with the reports or portions of it, that the report is confidential, and may establish reasonable conditions to ensure that confidentiality. The respondent's comments will be attached to the final report and the findings of the final report shall take into account the respondent's comments as well as all other evidence. The complainant's comments should be considered by the investigation committee and the report modified as appropriate prior to its submission. The investigation committee's report shall be submitted to the UT System Office of General Counsel for a review of its legal sufficiency prior to its submission to the President.

Investigation Decision, Notification and Appeal

- A. The President is the Deciding Official, and will make the final determination whether to accept the investigation report, its findings, and the recommended University actions. If this determination or recommendation varies from that of the Investigation Committee, the President will explain in written detail the basis for rendering a decision or recommendation different from that of the committee. The explanation of the President should be consistent with the definition of misconduct in research or other scholarly activity, the University's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The President may also return the report to the Investigation Committee with a request for additional fact finding and analysis. The determination of the President, together with the report of the Investigation Committee, constitutes the final report and decision.
- B. The Research Integrity Committee will notify the respondent and the complainant in writing of the final decision of the case. The President 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, but where PHS supported research is involved, the President will inform ORI before providing such notifications. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies, including submissions of the final report to ORI for PHS supported research or other appropriate agencies.
- C. At the discretion of the President, the respondent may appeal the decision, which could result in a reversal or modification of the University's findings of misconduct. If such an appeal is provided for, it must be completed within one hundred twenty (120) days of its filing, unless, with PHS supported research, ORI finds good cause for an extension, based upon the University's written request for an extension. With PHS supported research, if ORI grants an extension, it may direct the filing of periodic progress reports.
- D. With PHS supported research, unless an extension has been granted, the Research Integrity Officer must, within the one hundred twenty (120) day period for completing the investigation or the one hundred twenty (120) day period for completing the appeal, submit the following to ORI: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the University accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the University found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.
- E. With PHS supported research, the Research Integrity Officer must maintain and provide ORI upon request "records of research misconduct proceedings" as that is defined by 42 CFR 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records or misconduct proceedings must be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any PHS proceeding involving the misconduct allegation. The Research Integrity Officer is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of misconduct or of the University's handling of such an allegation.

Completion of Cases; Reporting Premature Closure to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be

pursued diligently. With PHS supported research, the Research Integrity Officer must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage, on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted or (2) of a finding of no misconduct at the inquiry stage, which must be reported to ORI.

University Administrative Actions

If the President determines that misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consideration with the Research Integrity Officer. The administrative actions may include: (1) withdrawal or correction of all pending or published abstracts and papers emanating from the research where misconduct was found (2) 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; (3) restitution of funds to the grantor agency as appropriate; and (4) other action appropriate to the misconduct.

Other Considerations

A. Termination of Employment or Resignation Prior to Completing Inquiry or Investigation

1. The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct proceeding or otherwise limit any of the University's responsibilities.
2. If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, 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.

B. Restoration of the Respondent's Reputation

Following a final finding of no misconduct, including ORI concurrence where required, the Research Integrity Officer will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the Research integrity Officer should consider notifying those individuals, aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of misconduct was previously publicized, and expunging all reference to the misconduct allegation from the respondent's personnel file. Any University actions to restore the respondent's reputation should first be approved by the President.

C. Protection of the Complainant, Witnesses and Committee Members

During the misconduct proceeding and upon its completion, regardless of whether the University or ORI determines that misconduct occurred, the Research Integrity Officer 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 of misconduct in good faith of any witnesses and committee members who cooperate in good faith with the misconduct proceeding. The President will determine, after consulting with the Research Integrity Officer, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective position or reputations or to counter potential or actual retaliation against them. The Research Integrity Officer is

responsible for implementing any steps the President approves.

D. Allegations Not Made in Good Faith

If relevant, the President will determine whether the complainant's allegations of misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the President determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

Record Retention

The Research Integrity Office will keep the complete file on all misconduct inquires and investigations regardless of funding, including the records of any inquiry or investigation and copies of all documents and other materials, for at least seven (7) years after completion of the case. For PHS supported research, ORI or other authorized HHS personnel will be given access to the records upon request.

Attachments:

Approval Signatures

Step Description	Approver	Date
	Kirk Calhoun: President/Prof of Medicine	06/2019
Executive Cabinet	Michelle Harris: Executive Assistant Senior	06/2019
Research Compliance Committee	Brigitte Tolson: Executive Assistant Senior	01/2019
Office of Legal Affairs	Terry Witter: VP Legal Affairs/ChiefLegalOf	01/2019
Faculty Senate	Vijaya Lella: Prof Of Biochemistry	01/2019
	Steven Idell: Sr VP Research & Grad Studies	01/2019